UTAH STATE BULLETIN

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Nancy L. Lancaster, Managing Editor

The *Utah State Bulletin (Bulletin)* is an official noticing publication of the executive branch of Utah state government. The Office of Administrative Rules, part of the Department of Administrative Services, produces the *Bulletin* under authority of Section 63G-3-402.

The Portable Document Format (PDF) version of the *Bulletin* is the official version. The PDF version of this issue is available at https://rules.utah.gov/. Any discrepancy between the PDF version and other versions will be resolved in favor of the PDF version.

Inquiries concerning the substance or applicability of an administrative rule that appears in the *Bulletin* should be addressed to the contact person for the rule. Questions about the *Bulletin* or the rulemaking process may be addressed to: Office of Administrative Rules, PO Box 141007, Salt Lake City, Utah 84114-1007, telephone 801-957-7110. Additional rulemaking information and electronic versions of all administrative rule publications are available at https://rules.utah.gov/.

The information in this *Bulletin* is summarized in the *Utah State Digest (Digest)* of the same volume and issue number. The *Digest* is available by e-mail subscription or online. Visit https://rules.utah.gov/ for additional information.

Office of Administrative Rules, Salt Lake City 84114

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Utah state bulletin.

Semimonthly.

- 1. Delegated legislation--Utah--Periodicals. 2. Administrative procedure--Utah--Periodicals.
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EXECUTIVE DOCUMENTS

Under authority granted by the Utah Constitution and various federal and state statutes, the Governor periodically issues **EXECUTIVE DOCUMENTS**, which can be categorized as either Executive Orders, Proclamations, and Declarations. Executive Orders set policy for the executive branch; create boards and commissions; provide for the transfer of authority; or otherwise interpret, implement, or give administrative effect to a provision of the Constitution, state law or executive policy. Proclamations call special or extraordinary legislative sessions; designate classes of cities; publish states-of-emergency; promulgate other official formal public announcements or functions; or publicly avow or cause certain matters of state government to be made generally known. Declarations designate special days, weeks or other time periods; call attention to or recognize people, groups, organizations, functions, or similar actions having a public purpose; or invoke specific legislative purposes (such as the declaration of an agricultural disaster).

The Governor's Office staff files **EXECUTIVE DOCUMENTS** that have legal effect with the Office of Administrative Rules for publication and distribution.

EXECUTIVE ORDER 2021-10

Requiring Increased Water Conservation Due to Drought Conditions

WHEREAS, 100% of the state is in drought and experiencing record high temperatures in June;

WHEREAS, the forecast predicts exceptionally poor to (potentially) worst-on-record water supply conditions this summer;

WHEREAS, a dry April was followed by an even drier May, with an average of 0.3 inches of precipitation accumulated in valley locations;

WHEREAS, a below-average statewide snowpack reached approximately 81% of normal and peaked 10 days early;

WHEREAS, soil moisture reached exceptionally low levels not previously seen since soil moisture monitoring began in 2006;

WHEREAS, these conditions have caused the streamflows around the state to remain below average;

WHEREAS, many of the reservoirs around the state that provide drinking and irrigation water are less than half of the capacity;

WHEREAS, these conditions were preceded by a record dry and near-record hot year in 2020;

WHEREAS, the United States Department of Agriculture currently has listed 28 primary and one contiguous county in Utah under the Secretarial Disaster Designation for drought;

WHEREAS, these extreme drought conditions are adversely and significantly impacting agribusiness and livestock production, as well as wildlife and natural habitats;

WHEREAS, increased recreation in dry vegetative conditions has contributed to an increased and prolonged threat of wildfire across the state;

WHEREAS, extreme drought conditions threaten access to safe, reliable drinking water from wells, streams, and reservoirs, and exacerbate water quality issues that affect recreational waters including an increase in harmful algal blooms;

NOW, THEREFORE, I, Spencer J. Cox, Governor of the State of Utah, hereby order the following for municipal and industrial water use:

1. As used in this Order:

a. "State facility" means a building or structure that is owned or controlled by the state or a state governmental entity.

- b. "State facility" does not mean a building or structure that is owned or controlled exclusively by:
- i. the legislative branch of the state;
- ii. the judicial branch of the state;
- iii. the Attorney General's Office;
- iv. the State Auditor's Office;
- v. the State Treasurer's Office;
- vi. the State Board of Education; or
- vii. an independent entity as defined in Utah Code § 63E-1-102.
- c. "State governmental entity" means any department, board, commission, institution, agency, or institution of higher

education.

2. When feasible, a state governmental entity should not water landscapes at a state facility between 10 a.m. and 6

p.m.

- 3. A state governmental entity shall do the following at all state facilities:
- a. Irrigate lawn areas only 2 times a week in Northern Utah and 3 times a week in Southern Utah
- b. Prioritize irrigation as follows:
- 1. Trees
- 2. Shrubs
- 3. Perennials
- 4. Annuals
- 5. Grass

c. Develop an implementation plan for updating irrigation technology with devices that are WaterSense certified and include rain and wind shutoff functions and soil moisture sensors;

- d. Manually shut off systems during rain and wind events in areas without rain and wind sensors;
- e. Audit and repair all landscape irrigation systems so they are operating at maximum efficiency;

f. Develop plans to replace inefficient plumbing fixtures with WaterSense certified low-flow fixtures;

g. Update facility-management technology to include metering for water-consuming processes related to irrigation, domestic, and mechanical systems;

h. Implement leak-detection and repair programs for both indoor and outdoor water use;

i. Conduct periodic checks of state facility restrooms, boiler rooms, etc., to ensure appliances are working at maximum efficiency;

j. Implement water efficient methods, technologies, and practices.

k. Check with the local water provider to follow restrictions in the local area.

I further ask all Utahns to join this call for conservation:

1. Cities and counties should:

a. Immediately consider implementing residential and commercial water restrictions for watering lawns during the current year and develop a supporting enforcement strategy;

- b. Implement the same practices that are recommended for state facilities at city, county, and institutional buildings.
- 2. Municipal and industrial water suppliers and secondary systems should:
- a. Implement water restrictions where appropriate.
- b. Encourage efficient landscape watering.
- c. Develop drought response plans.
- d. Notify customers in your system area of current water supply status and system plans.
- 3. Residential water users should follow best conservation practices:

a. Water at least one less time per week (average quarter-acre yard uses 3,000 gallons of water for each watering). Not to exceed lawn watering more than 2 times per week or no more than 3 times per week for Southern Utah.

- b. Don't water when it's windy.
- c. Don't water between 10 a.m.- 6 p.m. (Or 10 a.m.-8 p.m. in Southern Utah.)

d. <u>Prioritize your watering</u> to water the most valuable plants in your landscape first: Trees, shrubs, perennials, annuals then grass. Grass is resilient and will enter dormancy during times of drought and high temperatures and recover when conditions improve.

e. <u>Mow your lawn higher</u>. Set blades to 3-4 inches. Taller grass means deeper roots that can access water that is deeper in the soil. Tall grass also shades roots and soil to reduce evaporation loss.

f. Install a smart irrigation controller and receive a money-saving <u>rebate</u>. These devices connect to WiFi and access weather data and adjust the watering schedule to account for rain, temperature, humidity, UV index and even evapotranspiration. It connects to your phones so that you can control how often you water your landscape. <u>UtahWaterSavers.com</u>

g. Check with your local water provider to follow restrictions in your local water provider's jurisdiction.

This Order is effective immediately and shall remain in effect until otherwise modified, amended, rescinded, or superseded.

IN WITNESS, WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Utah. Done in Salt Lake City, Utah, on this, the 8th day of June, 2021.

(State Seal)

Spencer J. Cox Governor

ATTEST:

2021/10/EO

Deidre M. Henderson Lieutenant Governor

End of the Executive Documents Section

NOTICES OF PROPOSED RULES

A state agency may file a **PROPOSED RULE** when it determines the need for a substantive change to an existing rule. With a **NOTICE OF PROPOSED RULE**, an agency may create a new rule, amend an existing rule, repeal an existing rule, or repeal an existing rule and reenact a new rule. Filings received between <u>May 15, 2021, 12:00 a.m.</u>, and <u>June 01, 2021, 11:59 p.m.</u> are included in this, the <u>June 15, 2021</u>, issue of the *Utah State Bulletin*.

In this publication, each **PROPOSED RULE** is preceded by a **RULE ANALYSIS**. This analysis provides summary information about the **PROPOSED RULE** including the name of a contact person, anticipated cost impact of the rule, and legal cross-references.

Following the **RULE ANALYSIS**, the text of the **PROPOSED RULE** is usually printed. New rules or additions made to existing rules are underlined (<u>example</u>). Deletions made to existing rules are struck out with brackets surrounding them ([example]). Rules being repealed are completely struck out. A row of dots in the text between paragraphs (....) indicates that unaffected text from within a section was removed to conserve space. Unaffected sections are not usually printed. If a **PROPOSED RULE** is too long to print, the Office of Administrative Rules may include only the **RULE ANALYSIS**. A copy of each rule that is too long to print is available from the filing agency or from the Office of Administrative Rules.

The law requires that an agency accept public comment on **PROPOSED RULES** published in this issue of the *Utah State Bulletin* until at least <u>July 15, 2021</u>. The agency may accept comment beyond this date and will indicate the last day the agency will accept comment in the **RULE ANALYSIS**. The agency may also hold public hearings. Additionally, citizens or organizations may request the agency hold a hearing on a specific **PROPOSED RULE**. Section 63G-3-302 requires that a hearing request be received by the agency proposing the rule "in writing not more than 15 days after the publication date of the proposed rule."

From the end of the public comment period through <u>October 13, 2021</u>, the agency may notify the Office of Administrative Rules that it wants to make the **PROPOSED RULE** effective. The agency sets the effective date. The date may be no fewer than seven calendar days after the close of the public comment period nor more than 120 days after the publication date of this issue of the *Utah State Bulletin*. Alternatively, the agency may file a **CHANGE IN PROPOSED RULE** in response to comments received. If the Office of Administrative Rules does not receive a **NOTICE OF EFFECTIVE DATE** or a **CHANGE IN PROPOSED RULE**, the **PROPOSED RULE** lapses.

The public, interest groups, and governmental agencies are invited to review and comment on **Proposed Rules**. *Comment may be directed to the contact person identified on the* **Rule Analysis** *for each rule.*

PROPOSED RULES are governed by Section 63G-3-301, Rule R15-2, and Sections R15-4-3, R15-4-4, R15-4-5a, R15-4-9, and R15-4-10.

The Proposed Rules Begin on the Following Page

NOTICE OF PROPOSED RULE

TYPE OF RULE: Amendment		
Utah Admin. Code Ref (R no.):		Filing No. 53550

Agency Information

J			
1. Department:	Agriculture and Food		
Agency:	Plant Ind	dustry	
Street address:	350 N R	edwood Road	
City, state:	Salt Lak	e City, UT	
Mailing address:	PO Box	146500	
City, state, zip:	Salt Lak	e City, UT 84114-6500	
Contact person(s	;):		
Name:	Phone:	Email:	
Amber Brown	801- 982- 2204	ambermbrown@utah.gov	
Cody James	801- 982- 2376	codyjames@utah.gov	
Kelly Pehrson	801- kwpehrson@utah.gov 982- 2202		
Please address a	unctions	regarding information on this	

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

R68-27. Cannabis Cultivation

3. Purpose of the new rule or reason for the change:

Changes are needed to make this rule consistent with S.B. 192 that passed during the 2021 General Session.

4. Summary of the new rule or change:

The changes change "department" to "board" in Subsection R68-27-15(3) and add a reference to the statute that now specifies the responsibilities and makeup of the Cannabis Production Establishment Licensing Board. The changes also specify that in order to deny a renewal, violations must be significant, consistent with S.B. 192 (2021). Finally, the changes clarify that a cultivation facility must return an agent's badge to the Department of Agriculture and Food (Department) if the agent is no longer employed.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

There are no anticipated costs or savings to the state budget. The total number of cannabis cultivation licenses administered by the Department will not change with these changes, nor will the licensing fees charged by the Department.

B) Local governments:

There are no anticipated costs or savings to local governments because they do not regulate or operate as cannabis cultivation licensees.

C) Small businesses ("small business" means a business employing 1-49 persons):

There are no anticipated costs or savings to small businesses. The licensing fees and regulatory requirements for cannabis cultivation are not changing.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

There are no anticipated costs or savings to non-small businesses. The licensing fees and regulatory requirements for cannabis cultivation are not changing.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

There are no anticipated costs or savings to other persons because they do not regulate cannabis cultivation or operate as cultivation licensees.

F) Compliance costs for affected persons:

The compliance costs for affected persons will not change. The regulatory and fee requirements for cannabis cultivation licensees are not changing with these changes.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	FY2021	FY2022	FY2023
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0

Fiscal Benefits			
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head approval of regulatory impact analysis:

The Commissioner of the Department of Agriculture and Food, Craig W. Buttars, has reviewed and approves the regulatory impact analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

This rule will not have any fiscal impact on businesses in Utah.

B) Name and title of department head commenting on the fiscal impacts:

Craig W. Buttars, Commissioner

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Subsection	Subsection	Subsection
4-41a-103(5)	4-41a-204(2)(e)	4-41a-302(3)(b)(ii)

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

	Craig W. Buttars, Commissioner	Date:	05/18/2021
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R68. Agriculture and Food, Plant Industry. **R68-27.** Cannabis Cultivation.

R68-27-4. Cannabis Cultivation Facility Requirements.

1) A cannabis cultivation facility operating plan shall contain a blueprint or diagram of the facility containing the following information:

a) for indoor cannabis cultivation, the square footage of the area where cannabis is to be propagated;

b) for indoor cannabis cultivation, the square footage of the area where cannabis is to be grown;

c) the square footage of the area where cannabis is to be harvested;

d) the area where cannabis is to be dried, trimmed, and cured;

e) the square footage of the area where cannabis is to be packaged for wholesale;

f) the total square footage of the cultivation facility;

g) the square footage and location of areas to be used as a storeroom;

h) the location of the toilet facilities and hand washing facilities;

i) the location of a break room and location of personal belonging lockers; and

j) the location of the area to be used for loading and unloading of cannabis product for transportation.

2) For outdoor cannabis cultivation, the operating plan shall contain a detailed aerial photograph of the area on which the following information is shown:

a) the area where cannabis to be propagated; and

b) the area where cannabis is to be grown.

3) A cannabis cultivation facility operating plan shall detail the drying and curing methods to be used by the cannabis cultivation facility.

4) An outdoor cannabis cultivation facility shall outline the measures to be taken to ensure that product is kept from deterioration and contamination.

5) A cannabis cultivation facility shall have written emergency procedures to be followed in case of:

a) fire;

b) chemical spill; or

c) [other]another emergency at the facility.

6) A cannabis cultivation facility operating plan shall include:

a) a pest management plan;

b) a description of when and how fertilizers are to be applied during the production process;

c) procedures for water usage and waste water disposal; and

d) a waste disposal plan.

7) A cannabis cultivation facility shall have a written plan to handle potential recall and destruction of cannabis because of contamination.

8) A cannabis cultivation facility shall use a standardized scale that is registered with the department when cannabis is:

a) packaged for sale by weight;

b) bought and sold by weight; or

c) weighed for entry into the inventory control system.

9) A cannabis cultivation facility shall ensure that sanitary conditions are maintained on the premises, including ensuring proper and timely removal of litter and waste.

10) A cannabis cultivation facility shall compartmentalize each area in the facility based on function.

11) A cannabis cultivation facility shall limit access to the compartments to appropriate cannabis cultivation facility agents.

R68-27-8. Cannabis Cultivation Facility Agents.

1) A cannabis cultivation facility shall apply to the department for a cannabis cultivation facility agent registration card on a form provided by the department.

2) An application is not considered complete until the background check has been completed and the facility has paid the fee.

3) The cannabis cultivation facility agent registration card shall contain:

- a) the agent's full name;
- b) the name of the cannabis cultivation facility;
- c) the job title or position of the agent; and
- d) a photograph of the agent.

4) A cannabis cultivation facility is responsible to ensure that each cannabis cultivation facility agent has received department approved training pursuant to Section 4-41a-301.

5) A cannabis cultivation facility agent shall have a properly displayed identification badge which has been issued by the department while on the facility premises or while engaged in the transportation of cannabis.

6) Each cannabis cultivation facility agent shall have their state issued identification in their possession to certify the information on their badge is correct.

7) [A cannabis cultivation facility agent's identification badge shall be returned to the department immediately upon termination of their employment with the cannabis cultivation facility:]Upon termination, the identification badge of an agent shall be immediately returned to the department by the cannabis cultivation facility.

R68-27-15. Renewals.

1) A cannabis cultivation facility shall submit a notice of intent to renew the cannabis cultivation facility license and the licensing fee to the department by December 1st.

2) If the cannabis cultivation facility licensing fee and intent to renew the cannabis cultivation facility license are not submitted by December 31st the cannabis cultivation facility licensee may not continue to operate. 3) <u>Pursuant to Section 4-41a-03, [T]the [department]board</u> [may]shall renew a cannabis cultivation facility license unless [renewal would lead to]they identify a significant violation of the applicable laws and rules of the state.

KEY: marijuana, cannabis cultivation facility

Date of Enactment or Last Substantive Amendment: [May 15,] 2021

Authorizing, and Implemented or Interpreted Law: 4-41a-404(3); 4-41a-103(5); 4-41a-204(2)(e); 4-41a-302(3)(b)(ii); 4-41a-701(2); 4-41a-405(2)(b)(iv); 4-2-103(1)(i); 4-41a-801(1)

NOTICE OF PROPOSED RULE

TYPE OF RULE: New

Utah Admin. Code Ref (R no.):	Filing No. 53561

Agency Information

ment: Auditor			
Administration			
E310			
East Building			
Iress: 350 N State Street			
: Salt Lake City, UT 84114			
Contact person(s):			
Phone: Email:			
rlink 801- mteerlink@utah.gov 538- 1363			
w 538- 1356			

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

R123-7. Required Governmental Entities' Posting of Financial Information to Transparent Utah, formerly known as the Utah Public Finance Website

3. Purpose of the new rule or reason for the change:

The Legislature moved the Utah Public Finance Website from Division of Finance to Office of the State Auditor (OSA). Finance is repealing its rule, so OSA is imposing a substantially similar rule.

4. Summary of the new rule or change:

This rule requires that required governmental entities deliver certain fiscal data to the OSA.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

No additional fiscal impact. The same requirements currently exist under a different rule number for the Division of Finance.

B) Local governments:

No additional fiscal impact. The same requirements currently exist under a different rule number for the Division of Finance.

C) Small businesses ("small business" means a business employing 1-49 persons):

No additional fiscal impact. The same requirements currently exist under a different rule number for the Division of Finance.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

No additional fiscal impact. The same requirements currently exist under a different rule number for the Division of Finance.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

No additional fiscal impact. The same requirements currently exist under a different rule number for the Division of Finance.

F) Compliance costs for affected persons:

No additional fiscal impact. The same requirements currently exist under a different rule number for the Division of Finance.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table			
Fiscal Cost	FY2021	FY2022	FY2023
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0

Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits			
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head approval of regulatory impact analysis:

I have reviewed and approve this fiscal analysis. John Dougall, State Auditor

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

This proposed rule has no fiscal impact on business. This rule deals with government-to-government financial reporting and creates no additional burden.

B) Name and title of department head commenting on the fiscal impacts:

John Dougall, State Auditor

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Section 67-3-12	Section 63G-2-304	Section 63G-2-303
Section 63G-2-302	Section 63G-2-305	

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in

R15-1 for more information.)	the Utah State Bulletin. See Section 63G-3-302 and Rule	
	R15-1 for more information.)	

A)	Comments	will	be	accepted	07/15/2021	
un	til:					

1	0.	This	rule	change	MAY	07/22/2021
become effective on:						

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

Agency head	David	Date:	05/25/2021
or designee,	Stringfellow,		
and title:	Deputy State		
	Auditor		

R123. Auditor, Administration.

R123-7. Required Governmental Entities' Posting of Financial Information to Transparent Utah, formerly known as the Utah Public Finance Website.

R123-7-1. Purpose.

The purpose of this rule is to establish procedures related to the posting of reasonably complete and accurate financial information from participating entities to the Utah Public Finance Website.

R123-7-2. Authority.

This rule is established pursuant to Section 67-3-12, which authorizes the Office of the State Auditor to make rules governing the posting of financial information for participating entities to the Utah Public Finance Website.

R123-7-3. Definitions.

(1) Terms used in this rule are defined in Section 63G-1-201.
 (2) Additional terms are defined as follows:

(a) "Utah Public Finance Website" (UPFW) or "Transparent Utah" means the website created in Section 67-3-12 accessible to the public at transparent.utah.gov.

(b) "Division" means the Division of Finance of the Department of Government Operations.

(c) "FINET" means the State of Utah centralized accounting system.

(d) "Office" means the Office of the State Auditor.

R123-7-4. Public Financial Information.

(1)(a) Except as provided in subsection (1)(b), each participating entity shall submit to the Office its detail revenue and expense transactions from its general ledger accounting system to the UPFW at least quarterly and within one month after the end of the fiscal quarter.

(b) The Division shall ensure that detailed transactions for all participating state entities that post finances to FINET, are available to the Office.

(2)(a) Except as provided in subsection (2)(b), each participating entity shall submit to the Office its employee compensation

detail information on a basis consistent with its fiscal year to the UPFW at least once per year and within three months after the end of the fiscal year.

(b) The Division shall ensure that employee compensation detail information that is recorded in the central payroll system of the State is available to the Office.

(c) Employee compensation detail information will, at a minimum, break out the following amounts separately for each employee:

(i) total wages or salary;

(ii) total benefits, benefit detail that is protected by Subsection 63G-2-302(1)(g) may not be disaggregated;

(iii) incentive awards;

(iv) taxable allowances and reimbursements; and

(v) leave paid, if recorded separately from wages or salary in the participating state entity's payroll system.

(d) In addition, the following information will be submitted for each employee:

(i) name;

(ii) hourly rate for those employees paid on an hourly basis; and

(iii) job title

(3) An entity may not submit any data to the UPFW that is classified as private, protected, or controlled by Sections 63G-2-302, 63G-2-303, 63G-2-304, and 63G-2-305 or any other statute. All detail transactions or records are required to be submitted; however, the words "redacted" or "not provided" shall be inserted into any applicable data field in lieu of private, protected, or controlled information. The word "redacted" is preferred.

R123-7-5. UPFW Data Submission Procedures.

(1) Each entity that submits data for the UPFW must upload its files to the Office's State Reporting System.

(2) Each entity that submits data for the UPFW must submit it according to the following file specifications:

(a) The public financial information required in Section R123-7-4 shall be submitted to the Office in a pipe delimited text file. The detail file layout is available from the Office.

(b) Each transaction must contain the information required in the detail file layout including:

(i) Organization - Categorizes transactions within the entity's organization structure. If applicable, a transaction will contain at least two levels of meaningful organization. The Office may require an entity to report additional levels of organization detail.

(ii) Category - Categorizes transactions and describes the financial nature of the transaction. If applicable, a transaction will contain at least two levels of meaningful category. The Office may require an entity to report additional levels of category detail.

(iii) Fund - Categorizes transactions by fund types and individual funds. If applicable, a transaction will contain at least the identifiable fund. The Office may require an entity to report additional levels of fund detail.

(iv) Program -- Categorizes transactions by a plan of coordinated activities to accomplish specific objectives. Required reporting for all entities within the system of public education. If applicable, a transaction will contain at least the identifiable program. The Office may require an entity to report additional levels of program detail.

(v) Function -- Categorizes transactions according to the purpose of the financial activity. Required reporting for all entities within the system of public education. If applicable, a transaction will

contain at least two levels of meaningful function. The Office may require an entity to report additional levels of function detail.

(vi) Uniform Chart of Account Code -- Code provided by the Office that maps an entity's chart of account to the corresponding uniform chart of account for that entity type. If applicable, a transaction will map to the closest matching available code. The Office, in conjunction with the Utah State Board of Education, has promulgated a uniform chart of account for all local education agencies. The Office has also promulgated a uniform chart of account for all other local governmental entities that are not local education agencies.

KEY: Utah Public Financial Website, Transparent Utah, financial transparency, state employees, finance

Date of Enactment or Last Substantive Amendment: 2021 Authorizing, and Implemented or Interpreted Law: 67-3-12; 63G-2-304; 63G-2-302; 63G-2-305; 63G-2-303

NOTICE OF PROPOSED RULE

TYPE OF RULE: Amendment					
Utah Admin. Code	R131-3	Filing No.			
Ref (R no.):		53560			

Agency Information

1. Department:	Capitol I	Preservation Board (State)			
Agency:	Adminis	Administration			
Room no.:	Suite 12	0			
Building:	State Ca	apitol			
Street address:	350 N State Street, 120 State Capitol				
City, state:	Salt Lake City, UT 84114				
Mailing address:	PO Box 142110				
City, state, zip:	Salt Lake City, UT 84114-2110				
Contact person(s):					
Name:	Phone:	Email:			
Dana Jones	801- 538- 3074	danajones@utah.gov			
Please address questions regarding information on this					

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

R131-3. Use of Magnetometers on Capitol Hill

3. Purpose of the new rule or reason for the change:

The Utah Highway Patrol requested that this rule be amended to provide for closure of the Capitol Hill Complex in the event of a threat to the Capitol Hill Complex.

4. Summary of the new rule or change:

This amendment makes capitalization, spacing, and wording changes throughout this rule and inserted one number.

Amends Section R131-3-3 to: add a discretional duty for Capitol Hill Security personnel, add discretional Executive Director function in allowing access to Capitol Hill facilities and grounds, and add appointed officials to the category of state officials; change registration and magnetometer procedures to discretionary instead of mandatory status in Subsection (4)(a); specify that building entry points and access may be restricted; add Subsection (5) defining "Security level four" and Capitol Hill security personnel's mandatory and discretional duties during security level four, and define the Board's discretionary voting power during security level four.

Amends Section R131-3-4 to: add security level four to Subsections (1) and (2), change "the commander" to "Capitol Hill security personnel in Subsection (3), add that the Board has discretion to lower the security level by majority vote to Subsections (2) and (3), specify in Subsection (3) that only the Board members present at the requested meeting to discuss the decision to higher or lower security levels can vote, add to Subsection (3) that the Capitol Hill security personnel may also reduce the security level, and change the discretionary duty of Capitol Hill personnel in Subsection (4) from being able to ask persons passing through the magnetometers to show a concealed weapons permit to being able only to question that person on the facts relevant to their being able to lawfully carry a concealed firearm.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

There is no fiscal impact due to this filing because the modifications to internal capitol security modify procedure in a way that can be accomplished with current staff and resources.

B) Local governments:

There is no fiscal impact to local governments due to this filing because the modifications to internal capitol security modify procedure in a way that can be accomplished with current staff and resources.

C) Small businesses ("small business" means a business employing 1-49 persons):

There is no fiscal impact to small businesses due to this filing because the modifications to internal capitol security modify procedure in a way that can be accomplished with current staff and resources.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

There is no fiscal impact to non-small businesses due to this filing because the modifications to internal capitol security modify procedure in a way that can be accomplished with current staff and resources.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

There is no fiscal impact to other persons due to this filing because the modifications to internal capitol security modify procedure in a way that can be accomplished with current staff and resources.

F) Compliance costs for affected persons:

There is no fiscal impact to affected persons due to this filing because the modifications to internal capitol security modify procedure in a way that can be accomplished with current staff and resources.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	FY2021	FY2022	FY2023	
State Government	\$0	\$0	\$0	
Local Governments	\$0	\$0	\$0	
Small Businesses	\$0	\$0	\$0	
Non-Small Businesses	\$0	\$0	\$0	
Other Persons	\$0	\$0	\$0	
Total Fiscal Cost	\$0	\$0	\$0	
Fiscal Benefits				
State Government	\$0	\$0	\$0	
Local Governments	\$0	\$0	\$0	
Small Businesses	\$0	\$0	\$0	
Non-Small Businesses	\$0	\$0	\$0	
Other Persons	\$0	\$0	\$0	
Total Fiscal Benefits	\$0	\$0	\$0	

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There is no fiscal impact.

B) Name and title of department head commenting on the fiscal impacts:

Dana Jones, Executive Director

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Subsection	
63C-9-301(3)(a)	

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

Agency head or designee, and title:	Dana Jones, Executive Director	 05/27/2021
and the.		

R131. Capitol Preservation Board (State), Administration. R131-3. Use of Magnetometers on Capitol Hill. R131-3-1. Authority.

Subsection 63C-9-301(3)(a) requires the Capitol Preservation Board to make rules to govern, administer, and regulate Capitol Hill facilities and Capitol Hill grounds.

R131-3-2. Definitions.

(1) Terms used in this rule are defined in Section 63C-9-102.

(2) In addition:

(a) "Magnetometer" means a device that electronically detects the presence of ferrous metals from their effect on the magnetic field surrounding the earth.

(b) "Capitol Hill identification card" means a valid identification card issued or recognized by the [b]Board with a picture, individual name, and department identifying the person as a state elected or appointed official or state employee. A Capitol Hill identification card for this purpose does not include a card issued to an individual who [are]is not a state elected or appointed official or state employee.

(c) "Capitol Hill security personnel" means the Commissioner of the Utah Department of Public Safety, his or her designees, and Utah Highway Patrol, as provided in Sections 53-1-109 and 53-8-105.

R131-3-3. Security Levels.

(1) Notwithstanding any provision in this rule, under all security levels[<u>_]:</u>

(a) Capitol Hill security personnel may <u>increase</u>, or lower <u>security levels as provided in R131-3-4 and in all cases exercise the full authority and discretion granted to them by law to maintain the public safety and peace and to enforce the law.</u>

(b) The Executive Director may grant access to the Capitol Hill Complex to contractors and other third parties on a case-by- case basis as the Executive Director deems necessary or convenient for the operation, repair and/or maintenance of Capitol Hill Facilities and/or Capitol Hill Grounds.

(2) "Security level one"

(a) Any person entering <u>Capitol Hill [af]Facilit[y]ies</u> may be asked to register with <u>the</u>] Capitol Hill security personnel. No one is required to pass through a magnetometer.

(b) State elected <u>and appointed</u> officials and state employees holding valid Capitol Hill identification cards shall be allowed to enter at all entrances without registering or passing through a magnetometer.

(c) Building entry points and/or building access may be limited and/or restricted.

([e]d) Bag searches may not be conducted.

(3) "Security level two"

(a) Except as provided in Subsection (3)(b), all persons entering [a]Capitol Hill [f]Facilit[y]ies may be required to register with [the]Capitol Hill security personnel, and pass through a magnetometer.

(b) The [b]Board shall provide designated "employee entrances" where state elected <u>and appointed officials</u> and state employees holding valid Capitol Hill identification cards shall be allowed to enter without registering. [The–]Capitol Hill security personnel may require [S]state elected <u>and appointed officials</u> and state employees to pass through the magnetometers.

(c) [The-]Capitol Hill security personnel may require bag searches for persons entering [a]Capitol Hill [f]Facilit[y]ies including state elected and appointed officials and state employees holding a valid Capitol Hill identification card.

(d) Building entry points and/or building access may be limited and/or restricted.

(a) Except as provided in Subsection (4)(b), all persons entering [a]Capitol Hill [4]Facilit[<math>y]ies [shall]may be required to register with [the-]Capitol Hill security personnel, and pass through a magnetometer.

(b) The [b]Board shall provide designated "employee entrances" where state elected and appointed officials and state employees holding valid Capitol Hill identification cards shall be allowed to enter without registering. [The_]Capitol Hill security personnel [shall]may require state elected and appointed officials and state employees to pass through the magnetometers.

(c) [The-]Capitol Hill security personnel shall require bag searches for all persons entering [a]Capitol Hill [f]Facilit[y]ies, including state elected and appointed officials and state employees.

(d) Building entry points and/or building access may be limited and/or restricted.

(5) "Security level four"

(a) Partial and/or full closure to the public of the Capitol Hill Complex, including Capitol Hill Facilities, Capitol Hill Grounds and designated areas within the Capitol Hill Complex. Closures shall be based on an articulable significant threat to the safety of the public, and/or Capitol Hill Complex employees and elected and appointed officials, and/or the physical security of Capitol Hill Facilities and/or Capitol Hill Grounds. Capitol Hill security shall provide written notification articulating the facts and circumstances of the threat and closure to the Board within 48 hours of closure.

(b) Capitol Hill security personnel shall designate employee entrances for State elected and appointed officials and employees holding valid Capitol Hill identification cards.

(c) Capitol Hill security personnel may require State elected and appointed officials and employees to pass through magnetometers and/or be subject to bag searches.

(d) Building entry points and/or building access may be limited and/or restricted at the discretion of Capitol Hill security personnel.

(e) Emergency closure of the Capitol Complex shall last as long as the threat exists and closure is reasonably deemed necessary in response to the threat.

(f) In the event the Capitol Hill Complex remains closed after 30 days, Capitol Hill security shall provide to the Board in writing the justification for continued closure. The Board shall not be required to vote on the closure every 30 days, however, in the event written justification is not provided, the Capitol Hill Complex shall be reopened. Written justification for continued closure must be provided for every 30-day period of closure.

(g) The Board may, at any time, vote to end the closure as provided in R131-3-4, in which event the Capitol Hill Complex shall be reopened.

R131-3-4. Magnetometers.

(1) By this rule, the $[b]\underline{B}$ oard authorizes the use of magnetometers by Capitol Hill security personnel. Magnetometers may be used for security levels two<u>[-and]</u> three<u>and four</u>.

(2) Capitol Hill security personnel may use magnetometers in <u>Capitol Hill [\mathfrak{F}]Facilities and on [\mathfrak{the}]Capitol Hill [\mathfrak{g}]Grounds[-under the jurisdiction of the board] after [\mathfrak{the} commander of]Capitol Hill security personnel[, or that person''s superior,] determine[\mathfrak{s}] that there is a justification for increasing security precautions to level two, [or level]three_or four. Depending on where the threat is focused, different Capitol Hill [\mathfrak{f}]Facilities may be designated to be at different security levels. When practicable, the decision to increase security precautions at any Capitol Hill [\mathfrak{f}]Facility shall be made in consultation with the</u> $[\underline{e}]\underline{E}$ xecutive $[\underline{d}]\underline{D}$ irector. Otherwise, the person making the determination to change from one security level to another, shall notify the $[\underline{e}]\underline{E}$ xecutive $[\underline{d}]\underline{D}$ irector as soon as practicable after the decision is made.

(3) The $[\bullet]\underline{E}$ xecutive $[\underline{4}]\underline{D}$ irector shall notify the members of the $[\underline{b}]\underline{B}$ oard when the security level is changed. Any member of the $[\underline{b}]\underline{B}$ oard may request a meeting of the full $[\underline{b}]\underline{B}$ oard to examine further the decision to move to higher security levels. The Board may lower or raise the security level by a majority vote of the members present [forming a quorum of the Board]at the meeting. [The Commander]Capitol Hill security personnel may also reduce the security level depending on the security information received.

(4) The [b]Board and Capitol Hill security personnel, while using magnetometers in <u>Capitol Hill [f]F</u>acilities [under the authority of the board, shall not impact or infringe upon the rights of persons to keep and bear arms in accordance with Utah Constitution Article I, Section 6, and Title 76, Chapter 10, Part 5. A person carrying a concealed weapon by permit may be asked to show a valid, current concealed weapons permit before being allowed to enter the facility.]shall not impact or infringe upon the rights of persons to keep and bear arms in accordance with Utah Constitution Article I, Section 6, Title 53, Chapter 5, Part 7 and Title 76, Chapter 10, Part 5. A person carrying a concealed firearm may be reasonably questioned by Capitol Hill security personnel as to facts relevant to the lawfulness of the person's carrying of a concealed firearm before being allowed to enter Capitol Hill Facilities with a concealed firearm.

KEY: public buildings, state buildings, facilities use

Date of Enactment or Last Substantive Amendment: <u>2021[May 30,</u> 2002]

Notice of Continuation: May 2, 2017

Authorizing, and Implemented or Interpreted Law: 63C-9-301(3)

NOTICE OF PROPOSED RULE				
TYPE OF RULE: Amendment				
Utah Admin. Code Ref (R no.):	R313-19-100	Filing No. 53543		

Agency Information

1. Department:	Environmental Quality			
Agency:	Waste Management and Radiation Control, Radiation			
Building:	MASOB			
Street address:	195 N 1950 W			
City, state:	Salt Lake City, UT			
Mailing address:	PO Box 144880			
City, state, zip:	Salt Lake City, UT 84114-4880			
Contact person(s):				
Name:	Phone:	Email:		
Thomas Ball	801- 536- 0251	tball@utah.gov		

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

R313-19-100. Transportation

3. Purpose of the new rule or reason for the change:

The Division of Waste Management and Radiation Control (Division) received a comment from the Nuclear Regulatory Commission (NRC) in March of 2021 indicating that they had discovered an incompatibility in the Division's rule. The purpose of this amendment is to correct that incompatibility.

4. Summary of the new rule or change:

Section R313-19-100 incorporates by reference 10 CFR 71.97. This federal regulation requires certain transportation notifications to be submitted to state and federal agencies. Subsections R313-19-100(4)(a)(ii) and (iii) substitute "Director" for "Director, Division of Nuclear Safety, Office of Nuclear Security and Incident Response" and for "Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001".

The NRC commented that the notifications need to be sent to the NRC, as well as the state agency and indicated that to remain compatible with the federal program Utah needs to delete Subsections R313-19-100(4)(a)(ii) and (iii). Deleting these two subsections will not impact the Utah program because the federal regulations require the notifications to be submitted to the states as well as the federal agencies.

This amendment deletes Subsections R313-19-100(4)(a)(ii) and (iii).

Additionally, the Division has made minor formatting changes in this rule to correct formatting that does not conform to proper rulewriting format.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

It is not anticipated that there will be any cost or savings to the state budget due to this change because the change does not result in any changes to state agency operations.

B) Local governments:

It is not anticipated that there will be any cost or savings to local governments due to this change because the change does not result in any changes to local government agency operations. **C) Small businesses** ("small business" means a business employing 1-49 persons):

It is not anticipated that there will be any cost or savings to small businesses due to this change because the change does not require any small businesses that are required to comply with this rule to do anything different than they are currently doing.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

It is not anticipated that there will be any cost or savings to non-small businesses due to this change because the change does not require any non-small businesses that are required to comply with this rule to do anything different than they are currently doing.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

It is not anticipated that there will be any cost or savings to any other persons due to this change because the change does not require any persons that are required to comply with this rule to do anything different than they are currently doing.

F) Compliance costs for affected persons:

. . . .

It is not anticipated that there will be any additional compliance costs for affected persons due to the amendment to this rule because the amended rule does not require any affected persons to do anything different than they are currently doing.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table			
Fiscal Cost	FY2021	FY2022	FY2023
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits			

Net Fiscal Benefits	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
State Government	\$0	\$0	\$0

H) Department head approval of regulatory impact analysis:

The Executive Director of the Department of Environmental Quality, Kimberly D. Shelley, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

It is not anticipated that this rule change will have a fiscal impact on anyone who is required to comply with this rule. The change is being made in accordance with comments from the Nuclear Regulatory Commission and is necessary for the radiation control program in the to maintain compatibility with the federal regulations.

B) Name and title of department head commenting on the fiscal impacts:

Kimbery D. Shelley, Executive Director

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a

Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

0 5	Jalynn Knudsen, Interim Director	Date:	05/13/2021
and title:			

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.

R313-19. Requirements of General Applicability to Licensing of Radioactive Material.

R313-19-100. Transportation.

For purposes of Section R313-19-100, 10 CFR 71.0(c), 71.1(a), 71.3, 71.4, 71.13, 71.14(a), 71.15, 71.17, 71.19(a), 71.19(b), 71.19(c), 71.20 through 71.23, 71.47, 71.83 through 71.89, 71.97, 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, 71.127 through 71.137, and Appendix A to Part 71 (2019) are incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following:

(a) In 10 CFR 71.4 the following definitions:

(i) "close reflection by water";

(ii) "licensed material";

(iii) "optimum interspersed hydrogenous moderation";

(iv) "spent nuclear fuel or spent fuel"; and

(v) "state."

(2) The substitution of the [following-]date reference[:

(a)-] "October 1, 2011" for "October 1, 2008".

(3) The substitution of the following rule references:

(a) "<u>Rule_R313-36</u> (incorporating 10 CFR 34.31(b) by reference)" for "Sec. 34.31(b) of this chapter" as found in 10 CFR 71.101(g);

(b) "<u>Section_R313-15-502</u>" for reference to "10 CFR 20.1502";

(c) "<u>Rule</u> R313-14" for reference to "10 CFR Part 2 Subpart B";

(d) "Rule R313-32, 10 CFR Part 35," for reference to "10 CFR part 35";

(e) "<u>Subsection</u> R313-15-906(5)" for reference to "10 CFR 20.1906(e)";

(f) "<u>Subsection R313-19-100(5)</u>" for "Sec.71.5";

(g) "10 CFR 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, and 71.127 through 71.137" for "subpart H of this part" or for "subpart H" except in 10 CFR 71.17(b), 71.20(b), 71.21(b), 71.22(b), 71.23(b);

(h) "10 CFR 71.0(c), 71.1(a), 71.3, 71.4, 71.17(c)(2), 71.20(c)(2), 71.21(d)(2), 71.83 through 71.89, 71.97, 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, and 71.127 through 71.137" for "subparts A, G, and H of this part";

(i) "10 CFR 71.47" for "subparts E and F of this part"; and

(j) "10 CFR 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105, and 71.127 through 71.137" for "Sec. Sec. 71.101 through 71.137."

(4) The substitution of the following terms:

(a) "Director" for:

(i) "Commission" in 10 CFR 71.0(c), 71.17(a), 71.20(a), 71.21(a), 71.22(a), 71.23(a), and 71.101(c)(1);

(ii) ["Director, Division of Nuclear Safety, Office of Nuclear Security and Incident Response" in 10 CFR 71.97(c)(1), and 71.97(f)(1);

(iii) "Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555 0001" in 10 CFR 71.97(c)(3)(iii);

(iv)-]"NRC" in 10 CFR 71.101(f);

(b) "Director, the U.S. Nuclear Regulatory Commission, or an Agreement State" for "Commission" in 10 CFR 71.3;

(c) "The Governor of Utah" for:

(i) "the governor of a State" in 71.97(a);

(ii) "each appropriate governor" in 10 CFR 71.97(c)(1);

(iii) "the governor" in 10 CFR 71.97(c)(3);

(iv) "the governor of the state" in 10 CFR 71.97(e);

(v) "the governor of each state" in 10 CFR 71.97(f)(1);

(vi) "a governor" in 10 CFR 71.97(e);

(d) "State of Utah" for "State" in 71.97(a), 71.97(b)(2), and 71.97(d)(4);

(e) "the Governor of Utah's" for:

(i) "the governor's" in 10 CFR 71.97(a), 71.97(c)(3), 71.97(c)(3)(iii), 71.97(e), and 71.97(f)(1);

(ii) "governor's" in 10 CFR 71.97(c)(1), and 71.97(e);

(f) "Specific or general" for "NRC" in 10 CFR 71.0(c);

(g) "The Director at the address specified in <u>Sec</u>R313-12-110" for reference to "ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards" in 10 CFR 71.101(c)(1);

(h) "Each" for "Using an appropriate method listed in Sec. 71.1(a), each" in 10 CFR 71.101(c)(1);

(i) "The material must be contained in a Type A package meeting the requirements of 49 CFR 173.417(a)." for "The fissile material need not be contained in a package which meets the standards of subparts E and F of this part; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a)." as found in 10 CFR 71.22(a) and 71.23(a);

 $(j)\,$ "Licensee" for "licensee, certificate holder, and applicant for a COC"; and

(k) "Licensee is" for reference to "licensee, certificate holder, and applicant for a COC are."

(5) Transportation of licensed material

(a) Each licensee who transports licensed material outside the site of usage, as specified in the license issued by the Director, the U.S. Nuclear Regulatory Commission or an Agreement State, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations in 49 CFR parts 107, 171 through 180, and 390 through 397 (2009), appropriate to the mode of transport.

(i) The licensee shall particularly note DOT regulations in the following areas:

(A) Packaging--49 CFR part 173: subparts A (49 CFR 173.1 through 49 CFR 173.13), B (49 CFR 173.21 through 49 CFR 173.40), and I (49 CFR 173.401 through 49 CFR 173.477).

(B) Marking and labeling--49 CFR part 172: subpart D (49 CFR 172.300 through 49 CFR 172.338); and 49 CFR 172.400 through 49 CFR 172.407 and 49 CFR 172.436 through 49 CFR 172.441 of subpart E.

(C) Placarding--49 CFR part 172: subpart F (49 CFR 172.500 through 49 CFR 172.560), especially 49 CFR 172.500 through 49 CFR 172.519 and 49 CFR 172.556; and appendices B and C.

(D) Accident reporting--49 CFR part 171: 49 CFR 171.15 and 171.16.

(E) Shipping papers and emergency information--49 CFR part 172: subparts C (49 CFR 172.200 through 49 CFR 172.205) and G (49 CFR 172.600 through 49 CFR 172.606).

(F) Hazardous material employee training--49 CFR part 172: subpart H (49 CFR 172.700 through 49 CFR 172.704).

(G) Security plans--49 CFR part 172: subpart I (49 CFR 172.800 through 49 CFR 172.804).

(H) Hazardous material shipper[/<u>] or</u> carrier registration--49 CFR part 107: subpart G (49 CFR 107.600 through 49 CFR 107.606).

(ii) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(A) Rail--49 CFR part 174: subparts A through D (49 CFR 174.1 through 49 CFR 174.86) and K (49 CFR 174.700 through 49 CFR 174.750).

(B) Air--49 CFR part 175.

(C) Vessel--49 CFR part 176: subparts A through F (49 CFR 176.1 through 49 CFR 176.99) and M (49 CFR 176.700 through 49 CFR 107.720).

(D) Public Highway--49 CFR part 177 and parts 390 through 397.

(b) If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in <u>Subsection R313-19-100(5)(a)[paragraph (a) of this section]</u> to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, P.O. Box 144850, Salt Lake City, Utah 84114-4850.

KEY: licenses, reciprocity, transportation, exemptions Date of Enactment or Last Substantive Amendment:

2021 [February 14, 2020]

Notice of Continuation: April 8, 2021

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

NOTICE OF PROPOSED RULE

TYPE OF RULE: Repeal			
Utah Admin. Code Ref (R no.):	R380-200	Filing No. 53445	

Agency Information

0 3				
1. Department:	Health			
Agency:	Administration			
Room no.:	106			
Building:	Cannon			
Street address:	288 N 1460 W			
City, state:	Salt Lake City, UT 84116			
Mailing address:	PO Box 144004			
City, state, zip:	Salt Lake City, UT 84114-4004			
Contact person(s	Contact person(s):			
Name:	Phone:	Email:		
Carl Letamendi	801- 538- 7072	cletamendi@utah.gov		

Saperstein	538- 6430	V
Mike Martin	801- 538- 9205	mikemartin@utah.gov

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

R380-200. Patient Safety Surveillance and Improvement Program (PSSIP)

3. Purpose of the new rule or reason for the change:

This rule is being renumbered and also moved under a new title to better identify ownership of the PSSIP within the Utah Department of Health (UDOH).

4. Summary of the new rule or change:

Rule R380-200 is being repealed and then recreated within the new Title R429 under a separate filing. Rule R380-200 can be repealed without any effect on work currently performed by the UDOH. Therefore, this rule is no longer needed and is repealed in its entirety. (EDITOR'S NOTE: The proposed new Rule R429-1 is under Filing No. 53439 in this issue, June 15, 2021, of the Bulletin.)

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

There will be no fiscal impact to state budget because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

B) Local governments:

There will be no fiscal impact to local governments because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

C) Small businesses ("small business" means a business employing 1-49 persons):

There will be no fiscal impact to small businesses because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

There will be no fiscal impact to non-small businesses because all requirements outlined in this rule will still exist.

The requirements are only being moved to a different title and rule.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

There will be no fiscal impact to persons other than small businesses, non-small businesses, state, or local government entities because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

F) Compliance costs for affected persons:

There will be no fiscal impact to affected persons because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Regulatory	ipact lable	;	
Fiscal Cost	FY2022	FY2023	FY2024
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits			
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0

Net Fiscal	\$0	\$0	\$0
Benefits			

H) Department head approval of regulatory impact analysis:

The Executive Director of the Department of Health, Rich Saunders, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

There is no fiscal impact on businesses because there are no additional requirements.

B) Name and title of department head commenting on the fiscal impacts:

Rich Saunders, Executive Director

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Subsection 26-1-30(3)	Subsection 26-1-30(4)	Subsection 26-1-30(6)
Subsection 26-1-30(7)	Subsection 26-1-30(8)	Subsection 26-1-30(9)
Section 26-3-8		

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

NOTICES OF PROPOSED RULES

Agency Authorization Information

Agency head or designee, and title:	Saunders, Date: Itive Director	04/23/2021
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R380. Health, Administration.

[R380-200. Patient Safety Surveillance and Improvement Program (PSSIP).

R380-200-1. Purpose and Authority.

(1) These rules establish a Patient Safety Surveillance and Improvement program (PSSIP) which extends the past Sentinel Event Reporting program and consists of two components. The first component includes a reportable events program intended to meet public accountability and transparency needs at a state wide level. The second component uses the data obtained from the reportable events requirement as a foundation intended to develop state wide patient safety related improvement solutions.

(2) The rule requires certain health care facilities to report patient safety events specified in this rule as determined by PSSIP in consultation with the patient safety quality work group.

(3) Reporting requirements for this rule will provide an annual state-wide report released in March of each year for public accountability and transparency. Additionally, data obtained from the reporting requirements will be used to help the Utah Department of Health and Health Care Providers understand patterns of failures, identify and implement state-wide improvement interventions, and evaluate state-wide interventions for improved outcomes. The PSSIP intends to be consistent with national regulatory and quality organizational standards to which facilities currently report and may include requirements from the Joint Commission, Agency for Healthcare Research and Quality, American Association of Ambulatory Surgical Centers, DNV Healthcare, Patient Safety Organizations, National Healthcare Safety Network, Centers for Medicaid and Medicare, and the National Quality Forum. As national standards for condition reporting change so may the PSSIP reporting requirements. The quality work output of the PSSIP provides limited access to identifiable health information that facilities report.

(4) This rule is authorized by Utah Code Subsections "Utah Code Ann. Subsections 26-1-30(3), (4), (6), (7), (8), and (9)".

R380-200-2. Definitions.

(1) "Adverse event" is an injury associated with healthcare processes rather than the underlying patient condition or disease itself and that prolongs medical intervention or results in harm, disability or death.

(2) "Causal analysis" means a process for identifying the basic or causal factor(s) that underlie variation in performance, resulting in the occurrence or possible occurrence of a patient safety event, which may include a Root Cause Analysis, a Failure Mode and Effect Analysis, hazards analysis, evidence review, observation or any other relevant analytical process aimed at identifying and understanding contributing factors.

(3) "Contaminated" means contamination that can be seen with the naked eye, or with use of detection mechanisms in general use, as they become reported or known to the health care facility.

 — (4) "Harm Scale" is a systematic method to designate a patient's level of harm that includes;

(a) unsafe conditions,

(b) near miss which is an event that was stopped prior to reaching the patient,

(c) no harm,

(d) additional monitoring or treatment to prevent harm,

UTAH STATE BULLETIN, June 15, 2021, Vol. 2021, No. 12

 (e) temporary harm requiring intervention,

 (f) temporary harm requiring hospitalization,

 (g) permanent patient harm,

 (h) intervention to sustain life, or

 (i) patient death.

 (5) "Health care facility" as defined in Title 26, Chapter 21

Part 1, Section 2, (13)(a). (6) "Incident facility" means a facility where the patient

safety event occurred while in the facility or immediately following discharge within a certain time period defined by specifically by the type of event from that facility.

(7) "Medication Error" means medication administration:

(a) of a drug other than as prescribed or indicated;

(b) of a dose other than as prescribed or indicated;

- (c) to a patient who was not prescribed the drug;
- (d) at a time other than prescribed or indicated;
- (e) at a rate other than as prescribed or indicated;
 - (f) of an improperly prepared drug;

(g) by a means other than as prescribed or indicated; or (h) unintentional administration of a drug to a patient who

has a known allergy or drug interaction to the prescribed medication.

(8) "Patient safety events" are a compilation of serious, largely preventable, and harmful clinical adverse events that includes but are not limited to surgical events, product or device events, patient protection events, care management events, environmental events and eriminal events.

R380-200-3. Reporting of Patient Safety Events.

(1) Each facility shall report to the Department all patient safety events within seventy two hours of the facility's determination that a patient safety event may have occurred.

(2) Patient safety events are categorized as:

(a) Reportable Events with outcome assessed by harm scale; (b) Reportable Events resulting in permanent patient harm;

intervention to sustain life, or patient death: and

(c) Reportable Events referenced by other reporting rules.

(3) Patient Safety Events include:

(a) Reportable Events required to be reported through the reporting portal and with the outcome level assessed by a harm seale:

 (i) Surgery or procedures requiring consent performed on the wrong body part;

 (ii) Surgery or procedures requiring consent performed on the wrong patient;

 (iii) Incorrect surgery or procedures requiring consent performed on a patient;

 (iv) Unintended retention of a foreign object in a patient after surgery or other procedures requiring consent;

(v) Infant discharged to the wrong person;

 (vi) Neonatal hyperbilirubinemia, where bilirubin is greater than 25 milligrams per deciliter;

 (vii) Stage 3 or 4 pressure ulcers acquired after admission to the facility, except for pressure ulcers that progress from Stage 2 to Stage 3, if the Stage 2 ulcer was documented upon admission;

 (viii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance;

(ix) Unexpected flame or unanticipated smoke during and episode of care;

(x) Any care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed or certified health care provider;

(xi) Abduction of a patient of any age;

(xii) Non-consensual sexual contact on a patient, staff member, or visitor by another patient, staff member or unknown perpetrator while on the premises of the facility; or

(xiii) Elopement or disappearance of a patient with cognitive impairment for more than 4 hours;

 (b) Reportable Events resulting in permanent patient harm, intervention to sustain life, or patient death required to be reported to the reporting portal;

(i) Arising from Intraoperative or immediately post operative death of a patient who the facility classified prior to surgery as Anesthesia Surgical Assessment Class I or discharged home from an Ambulatory Surgical Center. "Intraoperative" means literally during surgery. "Immediately post operative" means within 24 hours after surgery, or other invasive procedure was completed, or after induction of anesthesia if surgery not completed;

(ii) Arising from the use of contaminated drugs, devices, or biologics provided by the facility;

 (iii) Arising from the use or function of a device in patient care in which the device is used for an off label use, except where the off-label use is pursuant to informed consent;

 (iv) Arising from intravascular air embolism that occurs while being cared for in the facility, except for intravascular air emboli associated with neurosurgical procedures;

(v) Arising from Patient suicide or unsuccessful attempt while in the facility or ER within 72 hours of discharge;

(vi) Arising from a medication error;

 (vii) Arising from a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products;

 (viii) Arising from hypoglycemia, the onset of hypoglycemia which occurs while the patient is being cared for in the facility;

 (ix) Arising from the irretrievable loss of an irreplaceable biological specimen;

(x) Arising from failure to follow up or communicate laboratory, pathology, or imaging test results;

(xi) Arising from an unintended electric shock while being cared for at a health care facility, excluding emergency defibrillation in ventricular fibrillation and electroconvulsive therapies;

(xii) Arising from a burn incurred from any source while being cared for in a facility;

(xiii) Arising from the use of restraints or bedrails while being cared for in a facility;

 (xiv) Arising from a fall while being cared for in a health care facility;

 (xv) Arising from a criminal assault or battery that occurs on the premises of the health care facility;

(xvi) Arising from the introduction of a metallic object into the MRI area;

(xvii) Arising from labor or delivery while being cared for in a facility; or

 (xviii) Of an infant born at gestation equal to or greater than 32 weeks excluding congenital causes.

(c) Reportable events required by other reporting rules:

The following set of reportable events is governed by other existing Utah law or rule and facility reporting to the reporting portal under this rule is not needed.

(i) Prolonged fluoroscopy with cumulative dose greater than 1500 rads to single field (R313-20-5);

(ii) Radiology to the wrong body region (R313-20-5);

(iii) Radiotherapy greater than 25% above the prescribed radiotherapy dose(R313-20-5);

(iv) Death or permanent loss of function related to a healthcare acquired infection (R386-705); and

(v) Provider Preventable Conditions (R414-1-29).

(4) If a facility suspects that a patient safety event may have occurred to a patient who was transferred from another facility, the receiving facility shall report the suspected patient safety event to the transferring facility.

(5) All facility required reports will be submitted through a secured reporting portal and consist of the following:

- (a) facility information; (b) patient information; (c) condition information
- (d) type of occurrence; (e) analysis findings; and

(f) corrective actions.

R380-200-4. Causal Analysis.

(1) The incident facility shall establish a causal analysis process.

(2) The incident facility shall designate a responsible individual to be the facility lead for each patient safety event.

(3) The incident facility may request the Department representative to participate in the facility's causal analysis in a consultative role to enhance the reliability and thoroughness of the causal analysis.

(4) The Department shall notify the facility's lead within 72 hours of receiving the patient safety event report whether the Department intends to participate in the facility's root cause analysis.

(5) Participation in the facility's causal analysis by the Department representative shall not be construed to imply Department endorsement of the facility's final findings or action plan.

(6) The incident facility and the Department shall each make reasonable accommodations when necessary to allow for the Department representative's participation in the causal analysis.

(7) If, during the review process, the Department representative discovers problems with the facility's processes that limit either the thoroughness or credibility of the findings or recommendations, the representative shall report these to the designated responsible individual orally within 24 hours of discovery and in writing within 72 hours.

(8) The facility shall conduct a causal analysis which is timely, thorough and credible to determine whether reasonable system changes would likely prevent a patient safety event in similar circumstances.

(9) The causal analysis shall:

(a) focus primarily on systems and processes, not individual performance;

 (b) progress from specific, direct causes in clinical processes to contributing causes in organizational processes;

 (c) seek to determine related and underlying causes for identified causes;

 (d) identify changes which could be made in systems and processes, either through redesign or development of new systems or processes, that would reduce the risk of such events occurring in the future; and

(c) may include a Known Complication Test Revision set of questions to be utilized when requesting a more thorough response from a unit or physician on evaluation of a known complication related to a procedure, treatment or test. These questions should address:

 (i) Whether the procedure/treatment/test was appropriate and Warranted and based on nationally recognized standards of care;

 (ii) Whether the complication is a known risk, was anticipated before the procedure and that the standard of care applied to mitigate the risk; (iii) Whether the complication was identified in a timely manner (i.e. at the time of the occurrence);

 (iv) Whether the complication treatment was according to the standard of care and in a timely manner; and

(v) Whether the treatment of the complication follows a nationally recognized standard of care.

(10) The Department shall determine the causal analysis to be complete if it:

(a) involves a complete review of the patient safety event including interviews with all readily identifiable witnesses and participants and a review of all related documentation;

 (b) identifies the human and other factors in the chain of events leading to the final patient safety event, and the process and system limitations related to the occurrence;

 (c) searches readily retrievable records to analyze the underlying systems and processes to determine where redesign might reduce risk;

 (d) makes reasonable attempts to identify and analyze trends of similar events which have occurred at the facility in the past;

(e) identifies risk points and their potential contributions to this type of event;

 (f) determines potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or that no such improvement opportunities exist; and

 (g) is based on the evidence from the research literature, data from other sources, or is derived from a formal organizational improvement strategy.

(11) The Department shall determine the causal analysis to be credible if it:

 (a) is led by someone with training in causal analysis processes and who was not involved in the patient safety event;

 (b) involves any necessary consultation with either internal or external experts in the processes in question who were not involved in the patient safety event;

 (c) includes participation by the leadership of the organization;

 (d) includes individuals most closely involved in the processes and systems under review;

 (d) is internally consistent, does not contradicting itself or leave obvious questions unanswered;

(e) provides an explanation for all findings of "not applicable" or "no problem"; and

(f) includes consideration of relevant, available literature.

R380-200-5. Reports and Action Plan.

(1) Within 60 calendar days of determination of the patient safety event, the incident facility shall submit to the department a final report with an action plan that:

(a) identifies changes that can be implemented to reduce risk or formulates a rationale for not implementing changes; and

(b) where improvement actions are planned, identifies who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.

(2) The incident facility shall provide a final report to the facility's administration and the Department in a Department approved electronic format that includes:

(a) type of harm;
 (b) contributing factors;

(c) preventability; and

(d) actions taken.

(3) The Department representative may submit a separate written dissenting report to the administrator of the incident facility and the Department if the Department representative identifies problems with the processes that limit the thoroughness or credibility of the findings and recommendations and that have not been corrected after reporting them to the designated responsible individual.

(4) The incident facility may seek review of the dissenting report by filing a request for agency as allowed by the Utah Administrative Procedures Act and Department rule.

(5) If a dissenting report is not challenged or is upheld on review:

(a) the facility shall include it in the facility's records of the causal analysis; and

(b) the Department may forward it, together with the facility's report, to the appropriate state agencies responsible for licensing the facility.

R380-200-6. Confidentiality.

(1) Information that the Department holds under this rule is confidential under the provisions of Title 26, Chapter 3. Because of the public interest to foster health care systems improvements, the Department may exercise its discretion under Section 26-3-8 and shall not release information collected under this rule to any person pursuant to the provisions of Subsections 26-3-7(1) or (8).

(2) Information produced or collected by a facility is confidential and privileged under the provisions of Title 26, Chapter 25.

R380-200-7. Extensions and Waivers.

(1) The Department may grant an extension of any time requirement of this rule if the facility demonstrates that the delay is due to factors beyond its control or that the delay will not adversely affect the required root cause analysis and the purposes of this rule.

(2) A facility requesting a waiver must submit the request to the Department representative prior to the deadline for the required action.

(3) The Department may grant a waiver of any other provision of this rule if the facility demonstrates that the waiver will not adversely affect the required root cause analysis and the purposes of this rule.

R380-280-8. Advisory Panel.

(1) The Department shall establish a multi-disciplinary advisory panel to assist in carrying out the Department's responsibilities under this rule.

(2) At least one representative from each healthcare system that is required to report under this rule shall be invited to be members of the advisory panel.

(3) Representatives from other Department patient safety initiatives and Health Care Associations shall be invited to participate and include but are not limited to:

(a) infection control,

(b) maternal and infant mortality,

(c) women and infant care, and

(d) other participants, as identified.

(4) Members of the advisory panel will complete confidentiality documents.

 (5) The advisory panel will meet at least quarterly in person or via electronic meeting.

(6) An annual report will be provided to the panel one month prior to public release for review and corrections.

R380-200-9. Reporting.

(1) The Department will report at a minimum one time a year in March on all events occurring in the state the previous year.

 (2) This report will be de identified and publicly available.

 (3) Internal reports may be generated for quality improvement initiatives and shared with members of the advisory panel.

 (4) An annual report of events will be requested from the governing program and incorporated in the annual March Patient Safety Report.

R380-200-10. Penalties.

An entity that violates any provision of this rule may be assessed a civil money penalty not to exceed the sum of \$5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor as provided in Section 26-23-6.

KEY: hospital, sentinel event, quality improvement, patient safety Date of Enactment or Last Substantive Amendment: December 30, 2015

Notice of Continuation: September 13, 2016

Authorizing, and Implemented or Interpreted Law: 26-1-30(2)(a); 26-1-30(2)(b); 26-1-30(2)(d); 26-1-30(2)(e); 26-1-30(2)(g); 26-3-8]

NOTICE OF PROPOSED RULE		
TYPE OF RULE: Repeal		
Utah Admin. Code R380-210 Filing No. Ref (R no.): 53444		

Agency Information

rigeney internation	•••		
1. Department:	Health		
Agency:	Adminis	tration	
Room no.:	106		
Building:	Cannon		
Street address:	288 N 1	460 W	
City, state:	Salt Lak	e City, UT 84116	
Mailing address:	PO Box	144004	
City, state, zip:	Salt Lak	e City, UT 84114-4004	
Contact person(s):			
Name:	Phone:	Email:	
Carl Letamendi	801- 538- 7072	cletamendi@utah.gov	
Stephanie Saperstein	801- 538- 6430	stephaniesaperstein@utah.go v	
Mike Martin	801- 538- 9205	mikemartin@utah.gov	
Please address questions regarding information on this			

notice to the agency.

General Information

2. Rule or section catchline:

R380-210. Health Care Facility Patient Safety Program

3. Purpose of the new rule or reason for the change:

This rule is being renumbered and also moved under a new title to better identify ownership of the Patient Safety Surveillance and Improvement Program (PSSIP) within the Utah Department of Health (UDOH).

4. Summary of the new rule or change:

Rule R380-210 is being repealed and then recreated within the new Title R429 under a separate filing. Rule R380-210 can be repealed without any effect on work currently performed by the UDOH. Therefore, this rule is no longer needed and is repealed in its entirety. (EDITOR'S NOTE: The proposed new Rule R429-2 is under Filing No. 53440 in this issue, June 15, 2021, of the Bulletin.)

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

There will be no fiscal impact to state budget because all requirements outlined in this rule will still exist, they are only being moved to a different title.

B) Local governments:

There will be no fiscal impact to local governments because all requirements outlined in the rule will still exist. The requirements are only being moved to a different title and rule.

C) Small businesses ("small business" means a business employing 1-49 persons):

There will be no fiscal impact to small businesses because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

There will be no fiscal impact to non-small businesses because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

There will be no fiscal impact to persons other than small businesses, non-small businesses, state, or local government entities because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

F) Compliance costs for affected persons:

There will be no fiscal impact to affected persons because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory In	Regulatory Impact Table		
Fiscal Cost	FY2022	FY2023	FY2024
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits			
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head approval of regulatory impact analysis:

The Executive Director of the Department of Health, Rich Saunders, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

There is no fiscal impact on businesses because there are no additional requirements.

B) Name and title of department head commenting on the fiscal impacts:

Rich Saunders, Executive Director

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

(
Subsection 26-1-30(3)	Subsection 26-1-30(4)	Subsection 26-1-30(6)
Subsection 26-1-30(7)	Subsection 26-1-30(8)	Subsection 26-1-30(9)
Section 26-3-8		

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

Agency head	Rich Saunders,	Date:	04/23/2021
or designee,	Executive Director		
and title:			

R380. Health, Administration.

[R380-210. Health Care Facility Patient Safety Program. R380-210-1. Purpose and Authority.

(1) This rule establishes the requirement for designated facilities to have a patient safety program and have in place effective

internal patient safety processes for specified problems. The reporting under this rule will also help the Department and health care providers to understand patterns of system failures in the health care delivery system and, where appropriate, to recommend statewide improvements to reduce the incidence of patient injuries. It limits access to identifiable health information that facilities report to the Department under this rule.

(2) This rule is authorized by Utah Code Subsections 26-1-30(2)(a), (b), (d), (e), and (g) and Section 26-3-8.

R380-210-2. Definitions.

"Adverse drug event" means any event involving a medication that causes or leads to patient harm, while the medication is in the control of the facility. Such events may be related to professional practice, health care products, procedures, and systems including: prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

"Facility" means a general acute hospital, critical access hospital, ambulatory surgical center, psychiatric hospital, orthopedie hospital, rehabilitation hospital, chemical dependency/substance abuse hospital or chronic disease hospital as those terms are defined in Title 26, Chapter 21.

(1) a change in monitoring the patient's condition;

(2) a change in therapy; or

(3) active medical or surgical treatment.

R380-210-3. Patient Injury Identification.

(1) Each facility shall implement processes to effectively identify and report to the Department the incidence of all:

(a) adverse drug events.

(2) Reporting to the Department may occur through established, statewide, electronic health care facility reporting systems managed by the Department.

(3) The report shall include codes applicable to the event from the current International Classification of Diseases Clinical Modification (ICD-CM) diagnosis coding, including codes for external cause of injury (E-codes) and codes for place of occurrence.

R380-210-4. Patient Injury Reduction.

 (1) Each facility shall implement processes that are effective in reducing the incidence of:

(a) adverse drug events.

R380-210-5. Confidentiality.

(1) Information that the Department holds under this rule is confidential under the provisions of Title 26, Chapter 3. Because of the public interest needs to foster health care systems improvements, the Department exercises its discretion under Section 26 3-8 and shall not release information collected under this rule to any person pursuant the provisions of Subsections 26 3-7(1) or (8).

(2) Information produced or collected by a facility is confidential and privileged under the provisions of Title 26, Chapter 25.

R380-210-6. Penalties.

As required by Section 63G-3-201(5): An entity that violates any provision of this rule may be assessed a civil money penalty not to exceed the sum of \$5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor as provided in Section 26-23-6. KEY: hospital, injury prevention, quality improvement, patient safety

Date of Enactment or Last Substantive Amendment: July 26, 2010 Notice of Continuation: September 13, 2016

Authorizing, and Implemented or Interpreted Law: 26-1-30(2)(a); 26-1-30(2)(b); 26-1-30(2)(d); 26-1-30(2)(c); 26-1-30(2)(g); 26-3-8]

NOTICE OF PROPOSED RULE

TYPE OF RULE: Amendment

Utah Admin. Code R384-415	Filing No.
Ref (R no.):	53559

Agency Information

1. Department:	Health		
Agency:		Control and Prev Promotion	ention,
Building:	Cannon	Health Building	
Street address:	288 N 1	460 W	
City, state:	Salt Lak	e City, UT 84116	
Mailing address:	PO Box	142106	
City, state, zip:	Salt Lak	e City, UT 84114-2106	
Contact person(s):			
Name:	Phone: Email:		
Braden Ainsworth	801- 538- 6187	tobaccorulescomments .gov	@utah
Christy Cushing	801- 538- 6260	tobaccorulescomments .gov	@utah
Please address questions regarding information on this notice to the agency.			

General Information

2. Rule or section catchline:

R384-415. Electronic Cigarette Substance Standards

3. Purpose of the new rule or reason for the change:

The proposed rule amendment to Rule R384-415 revises this rule to align with changes in Section 26-57-103, due to the passage of S.B. 1003 during the 2021 First Special Session. In addition, the Utah Department of Health (UDOH) seeks to incorporate the following additional changes related to the nicotine content in Subsection R384-415-5(1)(b), and the product quality requirements in Section R384-415-7 to address public comment concerns the UDOH received between March 15, 2021, and April 15, 2021.

4. Summary of the new rule or change:

The proposed rule amendment to Rule R384-415 revises this rule to align with changes to Section 26-57-103. These changes include replacing the word "standards" to "requirements to sell" in Section R384-415-1, adding the new definition of manufacturer sealed electronic cigarette product to Section R384-415-2, and throughout the rule replacing the term "manufacturer sealed electronic cigarette substance" with the new definition of "manufacturer sealed electronic cigarette product."

In addition, regarding the nicotine content limit change in R384-415-5(1)(b), the proposed Subsection rule amendment would prohibit a tobacco retailer from selling a manufacturer sealed electronic cigarette product with a nicotine concentration that is greater than 3% nicotine by weight per container, or exceeds a 36mg/mL concentration of nicotine effective September 1, 2021, allowing retailers two and a half months' time to anticipate the change, as it is very likely Utah tobacco retailers may avoid restocking their electronic cigarette product inventory by September 1, 2021, in anticipation of the U.S. Food and Drug Administration's (FDA) prohibition of electronic nicotine delivery systems (ENDS) and other deemed products on the market without premarket authorization of the sale 387j(c)(1)(A)(i), under 21 U.S.C. 21 U.S.C. 387j(a)(2)(A)(i), or 21 U.S.C. 387j(a)(2)(A)(ii), that is anticipated to be effective September 9, 2021.

Lastly, the proposed amendments in Section R384-415-7 are consistent in aligning with federal law requirements, and removes the 09/09/2021 date, as the FDA published a perspective in February 2021 noting their progress reviewing electronic cigarette product Premarket Tobacco Product Applications (PMTA), mentioning they may need additional time beyond the 09/09/2021 date to complete this process. On May 20, 2021, the FDA published an updated perspective, posting lists identifying over 6,000,000 products where a premarket application was submitted to FDA by 09/09/2020 via the PMTA process, allowing Utah's enforcement agencies the ability to research products with pending PMTA applications.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

Enactment of this proposed rule amendment is not expected to have any fiscal costs to the state budget, as existing allocated resources can cover an increase for Quit Line cessation services.

There are costs to Utahns who use electronic cigarettes, especially to those who use them now during the COVID-19 pandemic. An electronic cigarette product with a higher concentration of nicotine has a greater likelihood of being more addictive. Utahns who are addicted to nicotine products and want to quit are more likely to need tobacco cessation services to be able to quit successfully.

Currently, tobacco cessation services are provided by the UDOH through the state tobacco quit line and through quit services covered by health insurance plans. The continued sale of addictive products results in higher cost to the state tobacco quit line and health insurance companies to cover treatment for nicotine dependence.

In 2018, 13.3% of Utah's Medicaid recipients used electronic cigarettes. Reducing the nicotine content in electronic cigarettes sold in Utah could reduce electronic cigarette use among this population and subsequently decrease nicotine dependence treatment and healthcare expenditures for Medicaid clients, both in the short and long term. The Utah Medicaid program currently spends an estimated \$125,900,000 each year to treat tobacco-related diseases.

The Utah state quit line budget is approximately \$1,000,000 annually and all of the tobacco cessation services provided is free and confidential for users. The average state cost for treating nicotine dependence using the Utah quit line ranges between \$273 - \$300 per user. The Utah youth tobacco cessation program "My Life My Quit" (for both vaping and smoking), provided by the Utah tobacco quit line for individuals between the ages of 13 - 17, cost per user (counseling calls, text messaging, email support) is \$273. The Utah adult cessation program provided by the Utah tobacco quit line, cost per user (counseling calls, text messaging, email support, NRT) is \$300.

The Utah Department of Health Tobacco Prevention and Control Program's independent evaluator, Research Institute Triangle (RTI), states: "Simply because 5% nicotine makes up nearly 70% of sales, it does not mean that removing 5% nicotine products would result in a 70% drop in overall sales. Undoubtedly a very high percentage of regular/addicted users would either convert to the 3% (UDOH suspects this would be the vast majority, as many users are brand-loyal and would likely stick with their brand at the lower level rather than switch) or shop exclusively in vape shops for open systems (mods). Some percentage would possibly attempt to quit altogether, and some (likely a small) number might switch to cigarettes or smokeless (unintended consequence).

As this change has never been made however, there is no direct way of estimating that. There likely are ways to use simulation models to predict indirectly what the impact might be, but those would necessarily be based on many assumptions, likely drawn from other product types." In Utah, an estimated 30,000 youth currently use electronic cigarette products (12.4%). 44.5% of U.S. adolescents who vape are seriously interested in quitting, and 24.9% tried to quit in the past year (Smith, 2020). As a result of enactment of this proposed rule amendment, to hypothetically provide tobacco cessation services to 44.5% of Utah youth who vape (13,350) would cost Utah an estimated \$3,600,000. To hypothetically provide tobacco cessation services to 50% of young adults who vape (ages 18-34) (~55,000) would cost Utah an estimated \$16,600,000.

Effective 09/01/2021, the proposed rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette product from selling a manufacturer sealed electronic cigarette product with a nicotine concentration higher than 3% nicotine by weight per container, or exceeding a 36mg/mL concentration of nicotine. An electronic cigarette product with a higher concentration of nicotine has a greater likelihood of being more addictive, being that "the amount of nicotine delivered and the way in which it is delivered influences the addictiveness of a tobacco product" (Eaton DL et al., 2018; HHS, 2010b). Reducing the nicotine content in electronic cigarette products sold in Utah can aid in preventing youth and adult initiation of electronic cigarette products among Utahans who do not already smoke or vape. Electronic cigarette product use is more popular among Utah youth than all other tobacco products combined, therefore limiting youth access to highly addictive electronic cigarette products is critical for preventing a new epidemic of nicotine addiction.

Lastly, removing the 09/09/2021 date in Subsection R384-415-7(2) will have no fiscal impact to the state budget.

B) Local governments:

Enactment of this proposed rule amendment is not expected to have any fiscal impact on local governments, as local health departments will continue to conduct retail observations and investigations in accordance with respective state tobacco control laws, state administrative rules, and local health department regulations using existing allocated resources to enforce the amended rule.

Lastly, removing the 09/09/2021 date in Subsection R384-415-7(2) will have no fiscal impact to the local governments, and the FDA published a perspective dated 05/20/2021 identifies over 6,000,000 products where a PMTA application was submitted to the FDA by 09/09/2020 via the PMTA process, allowing Utah's enforcement agencies the ability to research products with pending PMTA applications.

C) Small businesses ("small business" means a business employing 1-49 persons):

The proposed rule amendment may result in a direct cost to small businesses that employ fewer than 50 employees and choose to sell manufacturer sealed electronic cigarette products. The proposed rule amendment may result in a direct fiscal cost to small businesses that primarily rely on the sale of tobacco products (retail tobacco specialty businesses) and operate under the North American Industry Classification System (NAICS) codes of 453991, 424940. Other small businesses that sell manufacturer sealed electronic cigarette products among other products they choose to sell include (445120) convenience stores, (447110) gas stations with convenience stores, (445110) supermarkets and other grocery stores, (452319) general merchandise and discount stores, (447190) other gasoline stations, (453991) tobacco stores, (424940) tobacco product merchant wholesalers, (453220) gift, novelty, and souvenir stores, (721110) hotels, (813410) civic and social organizations.

A review of UDOH combined local health department tobacco retail compliance check logs for fiscal year 2020 and cross-referenced with Utah Department of Workforce Services (DWS) Firm Find Data, shows that there are approximately 1,175 small businesses that sell some type of electronic cigarette products in Utah, or approximately 88% of Utah tobacco retailers. UDOH does not know how many of these 1,175 small businesses sell manufacturer sealed electronic cigarette products with nicotine concentrations higher than 3% by weight per container or mg/mL concentration of nicotine. exceed 36 Approximately 168 small business tobacco retailers, or approximately 12% choose to not sell electronic cigarette products and these businesses will not be affected by this rule amendment.

Effective 09/01/2021, the proposed rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette product from selling a manufacturer sealed electronic cigarette product with a nicotine concentration higher than 3% nicotine by weight per container or exceeding a 36mg/mL concentration of nicotine. Only tobacco retailers that currently sell manufacturer sealed electronic cigarette products with a higher nicotine concentration may experience a direct fiscal impact.

The two and a half months' notice of the nicotine content limit from 5% nicotine by weight per container, or 59mg/mL concentration of nicotine to equal to or less than 3% nicotine by weight per container or that do not exceed a 36mg/mL concentration of nicotine may reduce the direct fiscal cost impact on tobacco retailers. The two and a half months' time allows for tobacco retailers that sell manufacturer sealed electronic cigarette products with a nicotine concentration higher than 3% nicotine by weight per container, or exceeds a 36mg/mL concentration of nicotine to sell their current inventory of manufacturer sealed electronic cigarette products with a nicotine concentration of 5% nicotine by weight per container, or exceeds a 59mg/mL concentration of nicotine and avoid restocking these products before 09/01/2021. It is very likely Utah tobacco retailers may avoid restocking their electronic cigarette product inventory by 09/01/2021 in anticipation of the FDA's prohibition of ENDS and other deemed products on the market without premarket authorization of the sale of under 21 U.S.C. 387j(c)(1)(A)(i), 21 U.S.C. 387j(a)(2)(A)(i), or 21 U.S.C. 387j(a)(2)(A)(ii), that is anticipated to be effective 09/09/2021.

According to Statista's E-cigarette market share in the United States in 2020, by brand, 09/04/2020 report, five electronic cigarette manufacturer brands account for 97% of the U.S. market share: Juul (42%), Vuse (36%), blu (9%), Logic (8%) and Njoy (2%). Some of these electronic cigarette brands sell products with a nicotine concentration that is more than 3% nicotine by weight or 36mg/mL

concentration of nicotine. Nevertheless, all these brands also offer electronic cigarette products with less than a 3% nicotine by weight per container or 36 mg/mL concentration of nicotine. Since August 2019, disposable prefilled electronic cigarettes that have risen in popularity. A variety of disposable prefilled electronic cigarettes brands offer their products with nicotine concentrations equal to or less than 3% nicotine by weight per container or 36 mg/mL concentration of nicotine, including Puff Bar. Dinner Lady, Zaero Vape, Cali Bar, and Twst Disposable. Utah tobacco retailers that sell manufacturer sealed electronic cigarette products will continue to have the option to sell manufacturer sealed electronic cigarette products with a nicotine concentration equal to or less than 5% nicotine by weight per container, or that do not exceed a 59mg/mL concentration of nicotine until 09/01/2021, when Utah tobacco retailers will be required to only sell manufacturer sealed electronic cigarette products with a nicotine concentration equal to or less than 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine.

As indicated, the five electronic cigarette manufacturer brands listed above all offer manufacturer sealed electronic cigarette products that meet this 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine concentration requirement and there are also several popular disposable prefilled electronic cigarette brands that offer their products with nicotine concentrations that meet this 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine requirement.

The Utah Department of Health Tobacco Prevention and Control Program's independent evaluator, Research Institute Triangle (RTI), states: "Simply because 5% nicotine makes up nearly 70% of sales, it does not mean that removing 5% nicotine products would result in a 70% drop in overall sales. Undoubtedly a very high percentage of regular/addicted users would either convert to the 3% (UDOH suspects this would be the vast majority, as many users are brand-loyal and would likely stick with their brand at the lower level rather than switch) or shop exclusively in vape shops for open systems (mods). Some percentage would possibly attempt to quit altogether, and some (likely a small) number might switch to cigarettes or smokeless (unintended consequence). As this change has never been made however, there is no direct way of estimating that. There likely are ways to use simulation models to predict indirectly what the impact might be, but those would necessarily be based on many assumptions, likely drawn from other product types."

Lastly, removing the 09/09/2021 date in Subsection R384-415-7(2) will have a positive direct fiscal impact on small businesses that sell manufacturer-sealed electronic cigarette products, as these retailers may be allowed to continue to sell electronic cigarette products that comply with other sections of the proposed rule amendment and are pending review by the FDA under their PMTA process, should it take longer than 09/09/2021 to complete. FDA published a perspective dated 05/20/2021, that identifies over 6,000,000 products where a PMTA application was submitted to FDA by 09/09/2020 via the PMTA process, allowing Utah's enforcement agencies the ability to research products with pending PMTA applications.

The indirect costs to small businesses are unknown and difficult to determine, as the potential impact is unknown. UDOH does not know how many of these 1,175 small businesses choose to sell manufacturer sealed electronic cigarette products with nicotine concentrations higher than 3% by weight per container or exceed 36 mg/mL concentration of nicotine.

Similarly removing the 09/09/2021 date in Subsection R384-415-7(2) will have a positive direct fiscal impact to small businesses, as these retailers may be allowed to continue to sell electronic cigarette products that comply with other sections of the proposed rule pending review by the FDA under their PMTA process, should it take longer than 09/09/2021 to complete.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

The rule amendment may result in a direct cost to nonsmall businesses that employ more than 50 employees and choose to sell manufacturer sealed electronic cigarette products. The rule amendment may result in a direct fiscal cost to non-small businesses that sell manufacturer sealed electronic cigarette products among other products they choose to sell include (445120) convenience stores, (447110) gas stations with convenience stores, (445110) supermarkets and other grocery stores, (442319) general merchandise and discount stores, (447190) other gasoline stations, and (453220) gift, novelty, and souvenir stores.

A review of UDOH combined local health department tobacco retail compliance check logs for fiscal year 2020 and cross-referenced with DWS Firm Find Data, shows that there are approximately 208 non-small businesses that sell some type of electronic cigarette products in Utah, or approximately 12% of Utah tobacco retailers. UDOH does not know how many of these 208 non-small businesses sell manufacturer sealed electronic cigarette products with nicotine concentrations higher 3% by weight per container or exceed 36 mg/mL concentration of nicotine. Approximately 164 non-small business tobacco retailers, or approximately 9.6%, choose to not sell any electronic cigarette products and these businesses will not be affected by this rule amendment.

Effective 09/01/2021, the proposed rule amendment prohibits a tobacco retailer that sells a manufacturer sealed electronic cigarette product from selling a manufacturer sealed electronic cigarette product with a nicotine concentration higher than 3% nicotine by weight per container or exceeding a 36mg/mL concentration of nicotine. Only tobacco retailers that currently sell manufacturer sealed electronic cigarette products with a higher nicotine concentration may experience a direct fiscal impact. The two and a half months' notice of the nicotine content limit from 5% nicotine by weight per container, or 59mg/mL concentration of nicotine to equal to or less than 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine may reduce the direct fiscal cost impact on tobacco retailers. The two and a half months' time allows for tobacco retailers that sell manufacturer sealed electronic cigarette products with a nicotine concentration higher than 3% nicotine by weight per container, or exceeds a 36mg/mL concentration of nicotine to sell their current inventory of manufacturer sealed electronic cigarette products with a nicotine concentration of 5% nicotine by weight per container, or exceeds a 59mg/mL concentration of nicotine and avoid restocking these products before 09/01/2021. It is very likely Utah tobacco retailers may avoid restocking their electronic cigarette product inventory by 09/01/2021 in anticipation of the FDA's prohibition of ENDS and other deemed products on the market without premarket authorization of the sale of un under 21 U.S.C. 387j(c)(1)(A)(i), 21 U.S.C. 387j(a)(2)(A)(i), or 21 U.S.C. 387j(a)(2)(A)(ii), that is anticipated to be effective 09/09/2021.

According to Statista's E-cigarette market share in the United States in 2020, by brand, 09/04/2020 report, five electronic cigarette manufacturer brands account for 97% of the U.S. market share: Juul (42%), Vuse (36%), blu (9%), Logic (8%) and Njoy (2%). Some of these electronic cigarette brands sell products with a nicotine concentration that is more than 3% nicotine by weight or 36mg/mL concentration of nicotine. Nevertheless, all these brands also offer electronic cigarette products with less than a 3% nicotine by weight per container or 36 mg/mL concentration of nicotine. Since August 2019, disposable prefilled electronic cigarettes have risen in popularity. A variety of disposable prefilled electronic cigarettes brands offer their products with nicotine concentrations equal to or less than 3% nicotine by weight per container or 36 mg/mL concentration of nicotine, including Puff Bar, Dinner Lady, Zaero Vape, Cali Bar, and Twst Disposable. Utah tobacco retailers that sell manufacturer sealed electronic cigarette products will continue to have the option to sell manufacturer sealed electronic cigarette products with a nicotine concentration equal to or less than 5% nicotine by weight per container, or that do not exceed a 59mg/mL concentration of nicotine until 09/01/2021, when Utah tobacco retailers will be required to only sell manufacturer sealed electronic cigarette products with a nicotine concentration equal to or less than 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine.

As indicated, the five electronic cigarette manufacturer brands listed above all offer manufacturer sealed electronic cigarette products that meet this 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine concentration requirement and there are also several popular disposable prefilled electronic cigarette brands that offer their products with nicotine concentrations that meet this 3% nicotine by weight per container, or that do not exceed a 36mg/mL concentration of nicotine requirement.

The Utah Department of Health Tobacco Prevention and Control Program's independent evaluator, Research Institute Triangle (RTI), states: "Simply because 5% nicotine makes up nearly 70% of sales, it does not mean that removing 5% nicotine products would result in a 70% drop in overall sales. Undoubtedly a very high percentage of regular/addicted users would either convert to the 3% (we suspect this would be the vast majority, as many users are brand-loyal and would likely stick with their brand at the lower level rather than switch) or shop exclusively in vape shops for open systems (mods). Some percentage would possibly attempt to quit altogether, and some (likely a small) number might switch to cigarettes or smokeless (unintended consequence). As this change has never been made however, there is no direct way of estimating that. There likely are ways to use simulation models to predict indirectly what the impact might be, but those would necessarily be based on many assumptions, likely drawn from other product types."

Lastly, removing the 09/09/2021 date in Subsection R384-415-7(2) will have a positive direct fiscal impact on small businesses that sell manufacturer-sealed electronic cigarette products, as these retailers may be allowed to continue to sell product pending review by the FDA under their PMTA process, should it take longer than 09/09/2021 to complete. FDA published a perspective dated 05/20/2021, that identifies over 6,000,000 products where a PMTA application was submitted to FDA by 09/09/2020 via the PMTA process, allowing Utah's enforcement agencies the ability to research products with pending PMTA applications.

The indirect costs to non-small businesses are unknown and difficult to determine, as the potential impact is unknown. UDOH does not know how many of these 208 non-small businesses choose to sell manufacturer sealed electronic cigarette products with nicotine concentrations higher 3% by weight per container or exceed 36 mg/mL concentration of nicotine. Similarly removing the 09/09/2021 date in Subsection R384-415-7(2) will have a positive direct fiscal impact to non-small businesses, as these retailers may be allowed to continue to sell electronic cigarette products that comply with other sections of the proposed rule pending review by the FDA under their PMTA process, should it take longer than 09/09/2021 to complete.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

The proposed rule amendment to Rule R384-415 may result in an indirect cost or indirect benefit to persons, which can include both consumers who buy electronic cigarette products and individuals who work for small businesses or non-small businesses that sell electronic cigarette products. The indirect costs or indirect benefits to persons is unknown and difficult to determine, as the potential impact on consumers is unknown as they could choose to vape electronic cigarettes with a lower nicotine concentration, or they may choose to quit using electronic cigarettes as a result of enactment of this proposed rule amendment.

Likewise, the indirect costs or indirect benefits to persons employed at tobacco retail businesses is unknown and it is difficult to determine the impact on individual tobacco retail employees, who may be employed at either small businesses or non-small businesses which could be impacted as already indicated in 5C and 5D above, as a result of enactment of this proposed rule amendment.

Lastly, removing the 09/09/2021 date in Subsection R384-415-7(2) will have a positive direct fiscal impact to persons, as these retailers may be allowed to continue to sell electronic cigarette products that comply with other sections of the proposed rule pending review by the FDA under their PMTA process, should it take longer than 09/09/2021 to complete.

F) Compliance costs for affected persons:

The rule amendment to Rule R384-415 may result in an indirect cost or indirect benefit to persons, which can include both consumers who buy electronic cigarette products and individuals who work for small businesses or non-small businesses that sell electronic cigarette products.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

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Fiscal Cost	FY2021	FY2022	FY2023
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits			
State Government	\$0	\$0	\$0

Net Fiscal Benefits	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0

H) Department head approval of regulatory impact analysis:

The Executive Director of the Department of Health, Richard G. Saunders, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

The proposed rule amendment may result in a direct cost to businesses that sell manufacturer sealed electronic cigarette products and to businesses that primarily rely on the sale of tobacco products.

B) Name and title of department head commenting on the fiscal impacts:

Richard G. Saunders, Executive Director

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Subsection 26-57-103(2)

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

J	Richard G.	Date:	06/01/2021
or designee,	Saunders,		
and title:	Executive Director		

R384. Disease Control and Prevention, Health Promotion. R384-415. <u>Requirements to Sell</u> Electronic Cigarette <u>Products</u> [Substance Standards].

R384-415-1. Authority and Purpose.

(1) This rule is authorized by Section 26-57-103.

(2) The purpose of this rule is to establish <u>requirements to</u> <u>sell an electronic cigarette product regarding[standards for]</u> labeling, nicotine content, packaging, and product quality for nonmanufacturer sealed electronic cigarette substances and manufacturer sealed electronic cigarette [substances for the regulation of selling electronic cigarette.]products.

(3) A person may only sell an [non-manufacturer sealed]electronic cigarette substance, that is not a manufacturer sealed electronic cigarette substance, that is compliant with the established [standards and]requirements set forth in this rule.

(4) Beginning on July 1, 2021, a person may only sell a manufacturer sealed electronic cigarette <u>product[substance]</u> that is compliant with the established [standards and]requirements set forth in this rule.

(5) A product in compliance with this rule is not endorsed as safe.

R384-415-2. Definitions.

As used in this rule:

(1) "Child resistant" means the same as the term "special packaging" is defined in 16 C.F.R 1700.1(a)(4) and is tested in accordance with the method described in 16 C.F.R. 1700.20.

(2) "Department" means the Utah Department of Health.

(3) "Electronic cigarette" means the same as that term is defined in Section 76-10-101.

(4) "Electronic cigarette product" means the same as that term is defined in Section 76-10-101.

(5) "Electronic cigarette substance" means the same as that term is defined in Section 76-10-101.

(6) "Local health department" means the same as that term is defined in Subsection 26A-1-102(5).

(7) "Industrial hemp product" means the same as that term \underline{is} defined is in Section 4-41-102.

(8) "Manufacture" means the same as that term is defined in Section 26-57-102.

(9) "Manufacturer" means the same as that term is defined in Section 26-57-102.

(10) "Manufacturer sealed electronic cigarette substance" means the same as that term <u>is defined [is-]</u>in Section 26-57-102.

(11) "Mg/mL" means milligrams per milliliter, a ratio for measuring an ingredient, in liquid form, where accuracy is measured in milligrams per milliliter, or a percentage equivalent.

(12) "Manufacturer sealed electronic cigarette product" means the same as that term is defined in Section 26-57-102.

[(12)](13) "Nicotine" means the same as that term is defined in Section 76-10-101.

[(13)](14) "Non-manufacturer sealed electronic cigarette substance" means:

(a) an electronic cigarette substance that is not a manufacturer sealed electronic cigarette substance; and

(b) an electronic cigarette substance container the electronic cigarette manufacturer does intend for a consumer to open or refill.

[(14)](15) "Package" or "packaging" means a pack, box, carton, or container of any kind, or if no other container, any wrapping, in which an electronic cigarette substance or a manufacturer sealed electronic cigarette <u>product[substance]</u> is offered for sale, sold, or otherwise distributed to consumers.

[(+5)](16) "Permit" means the same as that term is defined in Section 26-62-101.

[(+6)](17) "Retailer" means any person who sells, offers for sale, exchanges, or offers to exchange for any form of consideration, a[n] non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette <u>product[substance]</u> to a consumer. This definition is without regard to the quantity of a[n] non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette <u>product[substance]</u> to a consumer. This definition is without regard to the quantity of a[n] non-manufacturer sealed electronic cigarette <u>product[substance]</u> sold, offered for sale, exchanged, or offered for exchange.

[(17)](18) "Transaction statement" means a statement, in paper or electronic form, which the manufacturer transferring ownership of the product certifies that the non-manufacturer sealed electronic cigarette substance or the manufacturer sealed electronic cigarette <u>product[substance]</u> is in compliance with the <u>requirements[standards]</u> in this rule.

R384-415-3. Labeling.

(1) The retailer shall ensure that <u>a</u>nicotine containing nonmanufacturer sealed electronic cigarette substance or <u>a</u> manufacturer sealed electronic cigarette <u>product[substance]</u> offered for sale to the consumer features on the product package label the required safety warning stating "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

(2) Consistent with 21 C.F.R. 1143.3, the safety warning statements required in Subsection (1), the required safety warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

(a) be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;

(b) be printed in at least 12-point font size and ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(c) be printed in conspicuous and legible Helvetica bold or Arial bold type, or other sans serif fonts, and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;

(d) be capitalized and punctuated as indicated in Subsection (1); and

(e) be centered in the warning area in which the text is required to be printed and positioned such that the text of the required

warning statement and the other information on the principal display panel have the same orientation.

(3) The retailer shall ensure that a non-manufacturer sealed electronic cigarette substance marketed as nicotine-free and offered for sale to the consumer features a safety warning stating "WARNING: Keep away from children and pets."

(4) The safety warning statements required in Subsection (3), the required safety warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:

(a) be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;

(b) be printed in at least 12-point font size and ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;

(c) be printed in conspicuous and legible Helvetica bold or Arial bold type, or other sans serif fonts, and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, consistent with the other printed material on the package;

(d) be capitalized and punctuated as indicated in Subsection (3); and

(c) be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on the principal display panel have the same orientation.

(5) A retailer will not be in violation of this section for packaging that:

(a) contains a health warning;

(b) is supplied to the retailer by the electronic cigarette <u>product[substance]</u> manufacturer, importer, or distributor, who has the required state, local, or tobacco tax license or permit, if applicable; and

(c) is not altered by the retailer in a way that is material to the requirements of this section.

(6) A non-manufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette <u>product[substance]</u> package that would otherwise be required to bear the safety warning in Subsection (1) or (3) but is too small or otherwise unable to accommodate a safety warning label with sufficient space to bear such information is exempt from compliance with the requirement provided that:

(a) the information and specifications required in Subsection (1) and (3) appear on the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information; or

(b) appear on a tag otherwise firmly and permanently affixed to the non-manufacturer sealed electronic- cigarette substance package or the manufacturer sealed electronic cigarette product[substance] package.

(7) In the case of Subsection (6)(a) or (b), the carton, outer container, wrapper, or tag will serve as the location of the principal display panels.

(8) The retailer shall ensure that an industrial hemp product that is a non-manufacturer sealed electronic cigarette substance or an industrial hemp product that is a manufacturer sealed electronic cigarette <u>product[substance]</u> is compliant with Title 4, Chapter 41, Part 1, Industrial Hemp and Section R68-26-5, unless:

(a) an industrial hemp product that is a non-manufacturer sealed electronic cigarette substance marketed as containing nicotine

and offered for sale or an industrial hemp product that is a manufacturer sealed electronic cigarette <u>product[substance]</u> marketed as containing nicotine and offered for sale is in compliance with the safety warning requirements in Subsection (1) and (2); or

(b) an industrial hemp product that is a non-manufacturer sealed electronic cigarette substance marketed as nicotine-free and offered for sale is exempt from the safety warning requirements in Subsection (3) and (4); if the product is compliant with Title 4, Chapter 41, Part 1, Industrial Hemp and Section R68-26-5.

R384-415-4. Prohibited Sales.

(1) The retailer shall be prohibited from selling a nonmanufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette <u>product[substance]</u> that is labeled as containing:

(a) additives that create the impression that a nonmanufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette <u>product[substance]</u> has a health benefit;

(b) additives that are associated with energy and vitality;

(c) illegal or controlled substances as identified in Section 58-37-3; and

(d) additives having coloring properties for emissions.

(2) The retailer shall be prohibited from selling an industrial hemp product that is a non-manufacturer sealed electronic cigarette substance or an industrial hemp product that is a manufacturer sealed electronic cigarette <u>product[substance]</u> unless it is compliant with Title 4, Chapter 41, Part 1, Industrial Hemp; Section R68-26-5; and Section R68-33-5.

R384-415-5. Nicotine Content.

(1) The retailer shall be prohibited from selling a nonmanufacturer sealed electronic cigarette substance or a manufacturer sealed electronic cigarette <u>product[substance]</u> to the consumer if the product is not compliant with the following:

(a) the nicotine concentration for a non-manufacturer sealed electronic cigarette substance is limited to 360 mg nicotine per container, or does not exceed a 24mg/mL concentration of nicotine; and

(b) the nicotine concentration for a manufacturer sealed electronic cigarette <u>product[substance]</u> is limited:

(i) to 5% nicotine by weight per container, or does not exceed a 59mg/mL concentration of nicotine, effective July 1, 2021: and

(ii) to 3% nicotine by weight per container, or does not exceed a 36mg/mL concentration of nicotine, effective September 1, 2021.

R384-415-6. Packaging.

(1) The retailer shall ensure that the packaging of a nonmanufacturer sealed electronic cigarette substance intended for sale to a consumer is certified as child resistant, and compliant with federal standards and law concerning child nicotine poisoning prevention.

(2) The retailer shall sell non-manufacturer sealed electronic cigarette substances and manufacturer sealed electronic cigarette <u>products[substances]</u> in the product's original packaging.

(3) The retailer shall be prohibited from repackaging or dispensing any non-manufacturer sealed electronic cigarette substance or any manufacturer sealed electronic cigarette <u>product[substance]</u> for retail sale. (4) The retailer shall be prohibited from refilling a manufacturer sealed electronic cigarette <u>product[substance]</u> that is not intended to be opened by a retailer or a consumer.

(5) The retailer shall ensure that an industrial hemp product that is a non-manufacturer sealed electronic cigarette substance or an industrial hemp product that is a manufacturer sealed electronic cigarette <u>product[substance]</u> is compliant with Title 4, Chapter 41, Part 1, Industrial Hemp; and Rule R68-26.

R384-415-7. Product Quality.

(1) <u>Consistent with 21 U.S.C 387j, n[N]</u>o manufacturer or retailer shall sell, offer for sale, or distribute an electronic cigarette, an electronic cigarette product, or an electronic cigarette substance unless the product complies with each of the relevant electronic cigarette product standards established by the U.S. Food and Drug Administration under 21 U.S.C. 387g(3).

(2) N[otwithstanding Subsection (3), after September 9, 2021, n]o manufacturer or retailer shall sell, offer for sale, or distribute an electronic cigarette, an electronic cigarette product, or an electronic cigarette substance unless the product has received marketing authorization from the U.S. Food and Drug Administration (FDA) under 21 U.S.C. 387j(c)(1)(A)(i), 21 U.S.C. 387j(a)(2)(A)(i), or 21 U.S.C. 387j(a)(2)(A)(ii) and related FDA regulations, policies, or actions.

(3) A manufacturer or retailer will not be in violation of Subsection (2) and may continue to sell, offer for sale, or distribute an electronic cigarette, an electronic cigarette product, or an electronic cigarette substance if:

(a) the manufacturer or retailer only sells, offers for sale, or distributes an electronic cigarette, an electronic cigarette product, or an electronic cigarette substance that is compliant with the requirements set forth in this rule;

(b) the manufacturer submitted a timely Pre-Market Tobacco application or Substantial Equivalent application to the FDA by September 9, 2020, verified by being listed on the FDA's website as a deemed new tobacco product with timely application; and

(c) the FDA has not issued a written marketing order and therefore the product's Pre-Market Tobacco application or Substantial Equivalent application is pending review by the FDA.

[(3)](4) This section will take effect on the date that manufacturers are required to secure marketing orders from the FDA to continue marketing their products in the United States.[—Any delays in enforcement efforts by FDA due to litigation will not impact the effective date of this section.]

R384-415-8. Record Keeping and Testing.

(1) The retailer shall provide the non-manufacturer sealed electronic cigarette substance transaction statements or manufacturer sealed electronic cigarette <u>product[substance]</u> transaction statements to the Department or the local health department within 14 calendar days of a request. The retailer shall ensure that the transaction statement includes manufacturer certifications that:

(a) the labeling <u>requirements[standards]</u> are compliant with Section R384-415-3;

(b) the nicotine content of a non-manufacturer sealed electronic cigarette substance is compliant with Subsection R384-415-5(1)(a) and the nicotine content of a manufacturer sealed electronic cigarette <u>product[substance]</u> is compliant with Subsection R384-415-5(1)(b);

(c) the packaging <u>requirements[standards]</u> are compliant with Section R384-415-6; and

(d) the product quality <u>requirements[standards]</u> are compliant with Section R384-415-7.

(2) The retailer shall provide evidence that supports the documents described in Subsection R384-415-8(1) to the Department or the local health department within 14 calendar days of a request.

(3) The retailer shall have access to the documents described in Subsections R384-415-8(1) and R384-415-8(2) for a period of two years after the retailer purchases the non-manufacturer sealed electronic cigarette substance or the manufacturer sealed electronic cigarette <u>product[substance]</u>.

R384-415-9. Enforcement.

(1) In enforcing or seeking penalties of any violation as set forth in this rule or Section 26-57-103, the Department and local health departments shall comply with the enforcement requirement in Title 26, Chapter 62, Part 3, Enforcement.

KEY: electronic cigarettes, nicotine, [standards,]Electronic Cigarette <u>Product and Nicotine Product</u> Regulation Act Date of Enactment or Last Substantive Amendment: [June 1,] 2021

Notice of Continuation: December 8, 2020

Authorizing, and Implemented or Interpreted Law: 26-57-103

NOTICE OF PROPOSED RULE		
TYPE OF RULE: No	ew	
Utah Admin. Code Ref (R no.):	R429-1	Filing No. 53439

Agency Information

Agency mornation		
1. Department:	Health	
Agency:	Patient Safety Program	
Room no.:	106	
Building:	Cannon	
Street address:	288 N 1460 W	
City, state:	Salt Lake City, UT 84116	
Mailing address:	PO 144004	
City, state, zip:	Salt Lake City, UT 84114-4004	
Contact person(s):		
Name:	Phone:	Email:
Carl Letamendi	801- 538- 7072	cletamendi@utah.gov
Stephanie Saperstein	801- 538- 6430	stephaniesaperstein@utah.go v
Mike Martin	801- 538- 9205	mikemartin@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule or section catchline:

R429-1. Patient Safety Surveillance and Improvement Program (PSSIP)

3. Purpose of the new rule or reason for the change:

This rule and its requirements existed under Rule R380-200 and is now being moved under the new Title R429. Rule R429-1 is a new rule that has been renumbered to align more appropriately with current, rule ownership within the Utah Department of Health (UDOH). Rule R429-1 has been updated to comply with rulewriting manual standards. Also, penalty language in Rule R429-1 has been updated for consistency with current statute. (EDITOR'S NOTE: The proposed repeal of Rule R380-200 is under Filing No. 53445 in this issue, June 15, 2021, of the Bulletin.)

4. Summary of the new rule or change:

This new, renumbered rule enforces a Patient Safety Surveillance and Improvement program (PSSIP) requiring certain health care facilities to report patient safety events specified therein; also, an annual statewide report summarizing past-year results is required in March of each year. Data is used by UDOH to understand patterns of failures, identify and implement state-wide improvement interventions, and evaluate state-wide interventions for improved outcomes.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

This rule iterates forward requirements of a repealed rule that is being renumbered. UDOH determines enactment of this rule will not create any cost or savings impact to the state budget or UDOH's budget, since the renumbered rule will not increase workload and can be carried out with existing budget.

B) Local governments:

This filing does not create any direct cost or savings impact to local governments since they are not directly affected by this rule; nor are local governments indirectly impacted because this rule does not create a situation requiring services from local governments.

C) Small businesses ("small business" means a business employing 1-49 persons):

There will be no fiscal impact to small businesses because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

There will be no fiscal impact to non-small businesses because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

There will be no fiscal impact to persons other than small businesses, non-small businesses, state, or local government entities because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule.

F) Compliance costs for affected persons:

There will be no fiscal impact to affected persons because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table				
Fiscal Cost	FY2022	FY2023	FY2024	
State Government	\$0	\$0	\$0	
Local Governments	\$0	\$0	\$0	
Small Businesses	\$0	\$0	\$0	
Non-Small Businesses	\$0	\$0	\$0	
Other Persons	\$0	\$0	\$0	
Total Fiscal Cost	\$0	\$0	\$0	
Fiscal Benefits				
State Government	\$0	\$0	\$0	
Local Governments	\$0	\$0	\$0	
Small Businesses	\$0	\$0	\$0	
Non-Small Businesses	\$0	\$0	\$0	
Other Persons	\$0	\$0	\$0	

NOTICES OF PROPOSED RULES

Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head approval of regulatory impact analysis:

The Executive Director of the Department of Health, Rich Saunders, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

There is no fiscal impact on businesses because there are no additional requirements.

B) Name and title of department head commenting on the fiscal impacts:

Rich Saunders, Executive Director

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Subsection	Subsection	Subsection
26-1-30(3)	26-1-30(4)	26-1-30(6)
Subsection	Subsection	Subsection
26-1-30(7)	26-1-30(8)	26-1-30(9)
Section 26-3-7	Section 26-3-8	

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

Agency head or designee, and title: Rich Saunders, Executive Director	2021
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R429. Health, Patient Safety Program.

R429-1. Patient Safety Surveillance and Improvement Program (PSSIP).

R429-1-1. Purpose and Authority.

(1) This rule establishes a Patient Safety Surveillance and Improvement program (PSSIP) which extends the past Sentinel Event Reporting program and consists of two components. The first component includes a reportable events program intended to meet public accountability and transparency needs at a statewide level. The second component uses the data obtained from the reportable events requirement as a foundation intended to develop statewide patient safety related improvement solutions.

(2) The rule requires certain health care facilities as defined in Subsection 26-21-2(13) to report patient safety events specified in this rule as determined by PSSIP in consultation with the patient safety quality work group.

(3) Reporting requirements for this rule will provide an annual statewide report released in March of each year for public accountability and transparency. Additionally, data obtained from the reporting requirements may be used to help the Utah Department of Health and health care providers understand patterns of failures, identify, and implement statewide improvement interventions, and evaluate statewide interventions for improved outcomes. The quality work output of the PSSIP provides limited access to identifiable health information that facilities report.

(4) This rule is authorized by Section 26-3-8; Subsection 26-1-3(3); Subsection 26-1-30(4); Subsection 26-1-30(6) through Subsection 26-1-30(9).

R429-1-2. Definitions.

(1) "Adverse event" means an injury associated with healthcare processes rather than the underlying patient condition or disease itself and that prolongs medical intervention or results in harm, disability, or death.

(2) "Causal analysis" means a process for identifying the basic or causal factor or factors that underlie variation in performance, resulting in the occurrence or possible occurrence of a patient safety event, which may include a root cause analysis, a failure mode and effect analysis, hazards analysis, evidence review, observation or any other relevant analytical process aimed at identifying and understanding contributing factors.

(3) "Contaminated" means contamination that can be seen with the naked eye, or with use of detection mechanisms in general use, as they become reported or known to the health care facility.

(4)	"Departme	ent" mea	ans the U	Jtał	n Departmen	t of Healt	h.
(5)	"Harm	scale"	means	а	systematic	method	of
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designating a patient's level of harm that includes:

(a) unsafe conditions; (b) near miss;

(c) no harm;

(d) additional monitoring or treatment to prevent harm;

(e) temporary harm requiring intervention;

- (f) temporary harm requiring hospitalization;
- (g) permanent patient harm;
- (h) intervention to sustain life; or

(i) patient death.

(6) "Health care facility" is used as defined in Subsection 26-21-2(13).

(7) "Immediately post-operative" means within 24 hours after surgery, or other invasive procedure was completed, or after induction of anesthesia if surgery not completed;

(8) "Incident facility" means a facility where the patient safety event occurred while in the facility or immediately following discharge within a certain time period defined by specifically by the type of event from that facility.

(9) "Intraoperative" means during surgery.

(10) "Medication Error" means medication administration:

(a) of a drug other than as prescribed or indicated;

(b) of a dose other than as prescribed or indicated;

(c) to a patient who was not prescribed the drug;

(d) at a time other than prescribed or indicated;

(e) at a rate other than as prescribed or indicated;

(f) of an improperly prepared drug;

(g) by a means other than as prescribed or indicated; or

(h) unintentional administration of a drug to a patient who has a known allergy or drug interaction to the prescribed medication.

(11) "Near miss" means stopping or aborting a procedure for the safety of the patient.

(12) "Patient safety events" mean a compilation of serious, largely preventable, and harmful clinical adverse events that includes surgical events, product or device events, patient protection events, care management events, environmental events and criminal events.

R429-1-3. Reporting of Patient Safety Events.

(1) Every facility shall report to the Department any patient safety event within 72 hours of the facility's determination that a patient safety event may have occurred.

(2) Patient safety events are categorized as:

(a) reportable events with outcome assessed by harm scale; (b) reportable events resulting in permanent patient harm, intervention to sustain life, or patient death; and

(c) reportable events in Subsection (3)(c).

(3) Patient safety events include:

(a) reportable events required to be reported through the reporting portal and with the outcome level assessed by a harm scale:

(i) surgery or procedures requiring consent performed on the wrong body part;

(ii) surgery or procedures requiring consent performed on the wrong patient;

(iii) incorrect surgery or procedures requiring consent performed on a patient;

(iv) unintended retention of a foreign object in a patient after surgery or other procedures requiring consent;

(v) infant discharged to the wrong person;

(vi) neonatal hyperbilirubinemia, where bilirubin is greater than 25 milligrams per deciliter;

(vii) stage 3 or 4 pressure ulcers acquired after admission to the facility, except for pressure ulcers that progress from Stage 2 to Stage 3, if the Stage 2 ulcer was documented upon admission;

(viii) any incident when a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance;

(ix) unexpected flame or unanticipated smoke during an episode of care;

(x) any care ordered or provided by someone impersonating a physician, nurse, pharmacist, or other licensed or certified health care provider;

(xi) abduction of a patient of any age;

(xii) non-consensual sexual contact on a patient, staff member, or visitor by another patient, staff member or unknown perpetrator while on the premises of the facility; or

(xiii) elopement or disappearance of a patient with cognitive impairment for more than 4 hours; and

(b) reportable events resulting in permanent patient harm, intervention to sustain life, or patient death required to be reported to the reporting portal;

(i) arising from Intraoperative or immediate post-operative death of a patient who the facility classified prior to surgery as Anesthesia Surgical Assessment Class I or discharged home from an ambulatory surgical center;

(ii) arising from the use of contaminated drugs, devices, or biologics provided by the facility;

(iii) arising from the use or function of a device in patient care when the device is used for an off-label use, except when the offlabel use is pursuant to informed consent;

(iv) arising from intravascular air embolism that occurs while being cared for in the facility, except for intravascular air emboli associated with neurosurgical procedures;

(v) arising from patient suicide or unsuccessful attempt while in the facility or ER within 72 hours of discharge;

(vi) arising from a medication error;

(vii) arising from a hemolytic reaction due to the administration of ABO or HLA incompatible blood or blood products;

(viii) arising from the onset of hypoglycemia that occurs while the patient is being cared for in the facility;

(ix) arising from the irretrievable loss of an irreplaceable biological specimen;

(x) arising from failure to follow up or communicate laboratory, pathology, or imaging test results;

(xi) arising from an unintended electric shock while being cared for at a health care facility, excluding emergency defibrillation in ventricular fibrillation and electroconvulsive therapies;

(xii) arising from a burn incurred from any source while being cared for in a facility;

(xiii) arising from the use of restraints or bedrails while being cared for in a facility;

(xiv) arising from a fall while being cared for in a health care facility;

(xv) arising from a criminal assault or battery that occurs on the premises of the health care facility;

(xvi) arising from the introduction of a metallic object into the MRI area;

(xvii) arising from labor or delivery while being cared for in a facility; or

(xviii) of an infant born at gestation equal to or greater than 32 weeks excluding congenital causes; and

(c) reportable events required by other reporting rules; and (d) reportable events governed by other existing law or rule and are not required to be reported to the reporting portal:

(i) prolonged fluoroscopy with cumulative dose greater than 1500 rads to single field, R313-30-5;

(ii) radiology to the wrong body region, R313-30-5;

(iii) radiotherapy greater than 25% above the prescribed radiotherapy dose, R313-30-5;

(iv) death or permanent loss of function related to a healthcare acquired infection, R386-705; and

(v) provider preventable conditions, R414-1-28.

(4) If a facility suspects that a patient safety event may have occurred to a patient who was transferred from another facility, the receiving facility shall report the suspected patient safety event to the transferring facility.

(5) Each facility-required report will be submitted through a secured reporting portal and consist of the following:

(a) facility information;

(b) patient information;

(c) condition information;

(d) type of occurrence;

(e) analysis findings; and

(f) corrective actions.

R429-1-4. Causal Analysis.

(1) The incident facility shall establish a causal analysis process.

(2) The incident facility shall designate a responsible individual to be the facility lead for each patient safety event.

(3) The incident facility may request the Department representative to participate in the facility's causal analysis in a consultative role to enhance the reliability and thoroughness of the causal analysis.

(4) The Department shall notify the facility's lead within 72 hours of receiving the patient safety event report whether the Department intends to participate in the facility's causal analysis.

(5) Participation in the facility's causal analysis by the Department representative may not be construed to imply Department endorsement of the facility's final findings or action plan.

(6) The incident facility and the Department shall each make reasonable accommodations when necessary to allow for the Department representative's participation in the causal analysis.

(7) If, during the review process, the Department representative discovers problems with the facility's processes that limit either the thoroughness or credibility of the findings or recommendations, the representative shall orally report these to the designated responsible individual within 24 hours of discovery and in writing within 72 hours.

(8) The facility shall conduct a causal analysis that is timely, thorough, and credible to determine whether reasonable system changes would likely prevent a patient safety event in similar circumstances.

(9) The causal analysis shall:

(a) focus primarily on systems and processes, not individual performance;

(b) progress from specific, direct causes in clinical processes to contributing causes in organizational processes;

(c) seek to determine related and underlying causes for identified causes:

(d) identify changes that could be made in systems and processes, either through redesign or development of new systems or processes, that would reduce the risk of such events occurring in the future; and

(e) may include a set of questions to be utilized when requesting a more thorough response from a unit or physician on evaluation of a known complication related to a procedure, treatment, or test; and

(f) these questions should address whether:

(i) the procedure, treatment or test was appropriate, warranted and based on nationally recognized standards of care;

(ii) the complication is a known risk, was anticipated before the procedure, and that the standard of care applied to mitigate the risk;

(iii) the complication was identified in a timely manner;

(iv) the complication treatment was according to the standard of care and in a timely manner; and

(v) the treatment of the complication follows a nationally recognized standard of care.

(10) The Department shall determine the causal analysis to be complete if it:

(a) involves a complete review of the patient safety event including interviews with each readily identifiable witness, participant, and a review of related documentation;

(b) identifies the human and other factors in the chain of events leading to the final patient safety event, and the process and system limitations related to the occurrence;

(c) searches readily retrievable records to analyze the underlying systems and processes to determine where redesign might reduce risk;

(d) makes reasonable attempts to identify and analyze trends of similar events that have occurred at the facility in the past;

(e) identifies risk points and their potential contributions to this type of event;

(f) determines potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or that no such improvement opportunities exist; and

(g) is based on the evidence from the research literature, data from other sources, or is derived from a formal organizational improvement strategy.

(11) The Department shall determine the causal analysis to be credible if it:

(a) is led by someone with training in causal analysis processes and who was not involved in the patient safety event:

(b) involves any necessary consultation with either internal or external experts in the processes in question who were not involved in the patient safety event;

(c) includes participation by the leadership of the organization;

(d) includes individuals most closely involved in the processes and systems under review;

(d) is internally consistent, does not contradict itself or leave obvious questions unanswered;

(e) provides an explanation for findings, including findings deemed inapplicable, and

(f) includes consideration of relevant, available literature.

R429-1-5. Reports and Action Plan.

(1) Within 60 calendar days of determination of the patient safety event, the incident facility shall submit to the Department a final report with an action plan that:

(a) identifies changes that can be implemented to reduce risk or formulates a rationale for not implementing changes; and

(b) where improvement actions are planned, identifies who is responsible for implementation, when the action will be implemented including any pilot testing, and how the effectiveness of the actions will be evaluated.

(2) The incident facility shall provide a final report to the facility's administration and the Department in a Department-approved electronic format that includes:

(a) type of harm;

(b) contributing factors;

(c) preventability; and

(d) actions taken.

(3) The Department representative may submit a separate written dissenting report to the administrator of the incident facility and the Department if the Department representative identifies problems with the processes that limit the thoroughness or credibility of the findings and recommendations and that have not been corrected after reporting them to the designated responsible individual.

(4) The incident facility may seek review of the dissenting report by filing a request for agency review as allowed by the Utah Administrative Procedures Act and Department rule.

(5) If a dissenting report is not challenged or is upheld on review:

(a) the facility shall include it in the facility's records of the causal analysis; and

(b) the Department may forward it, together with the facility's report, to the appropriate state agencies responsible for licensing the facility.

R429-1-6. Confidentiality.

(1) Information received and stored by the Department under this rule is confidential and may only be disclosed with Department approval under specific, enumerated conditions provided by Section 26-3-7. The Department is authorized to exercise its discretion to disclose information in accordance with Section 26-3-8.

(2) The Department may not release information collected under this rule to any person pursuant to Subsection 26-3-7(1) or Subsection 26-3-7(8).

(3) Information provided by a facility to the Department under this rule is privileged, as provided by Title 26, Chapter 25, Confidential Information Release.

R429-1-7. Extensions and Waivers.

(1) The Department may grant an extension of any reporting time requirement of this rule, if the facility demonstrates that:

(a) the delay is due to factors beyond its control;

(b) the delay will not adversely affect the purposes of this rule; or

(c) any other reason acceptable to the Department.

(2) A facility requesting a waiver must submit the request to the Department representative prior to the deadline for the required action.

(3) The Department may grant a waiver of any other provision of this rule if the facility demonstrates that the waiver will not adversely affect the required root cause analysis and the purposes of this rule.

R429-1-8. Advisory Panel.

(1) The Department shall establish a multi-disciplinary advisory panel to assist in carrying out the Department's responsibilities under this rule.

(2) At least one representative from each healthcare system that is required to report under this rule shall be invited to be members of the advisory panel.

(3) Representatives from other Department patient safety initiatives and Health Care Associations shall be invited to participate and include:

(a) infection control;

(b) maternal and infant mortality;

(c) women and infant care; and

(d) other participants, as identified.

(4) Members of the advisory panel will complete confidentiality documents.

(5) The advisory panel will meet at least quarterly in person or via electronic meeting.

(6) An annual report will be provided to the panel one month prior to public release for review and corrections.

R429-1-9. Reporting.

(1) The Department will report at least one time per year in March all events occurring in the state the previous year.

(2) This report and information contained therein will be de-identified and publicly available.

(3) Internal reports may be generated for quality improvement initiatives and shared with members of the advisory panel.

R429-1-10. Penalties.

Any association, or corporation, or the officers of any of them, that violates any provision of this rule may be assessed a judicial civil or administrative money penalty not to exceed the sum of \$5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor as provided in Section 26-23-6.

KEY: hospital, sentinel event, quality improvement, patient safety

Date of Enactment or Last Substantive Amendment: 2021 Authorizing, and Implemented or Interpreted Law: 26-1-30(3); 26-1-30(4); 26-1-30(6); 26-1-30(7); 26-1-30(8); 26-1-30(9); 26-3-7; 26-3-8

NOTICE OF PROPOSED RULE

TYPE OF RULE: New		
Utah Admin. Code R429-2	Filing No.	
Ref (R no.):	53440	

Agency Information

1. Department:	Health			
Agency:	Patient Safety Program			
Room no.:	106			
Building:	Cannon			
Street address:	288 N 1	460 W		
City, state:	Salt Lak	e City, UT 84116		
Mailing address:	PO 1440	004		
City, state, zip:	Salt Lak	e City, UT 84114-4004		
Contact person(s	Contact person(s):			
Name:	Phone:	Email:		
Carl Letamendi	801- 538- 7072	cletamendi@utah.gov		
Stephanie Saperstein	801- 538- 6430	stephaniesaperstein@utah.go v		
Mike Martin	801- mikemartin@utah.gov 538- 9205			
Please address questions regarding information on this notice to the agency.				

General Information

2. Rule or section catchline:

R429-2. Health Care Facility Patient Safety Program

3. Purpose of the new rule or reason for the change:

This rule and its requirements existed under Rule R380-210 and is now being moved under the new Title R429. Rule R429-2 is a new rule that has been renumbered to align more appropriately with current, rule ownership within the Utah Department of Health (UDOH). Rule R429-2 has been updated to comply with rulewriting manual standards. Also, penalty language in Rule R429-2 has been updated for consistency with current statute. (EDITOR'S NOTE: The proposed repeal of Rule R380-210 is under Filing No. 53444 in this issue, June 15, 2021, of the Bulletin.)

4. Summary of the new rule or change:

This new, renumbered rule establishes the requirement for designated facilities to have a patient safety program and have in place effective internal patient safety processes for specified problems. The reporting under this rule will also help UDOH and health care providers understand patterns of system failures in the health care delivery system and, where appropriate, recommend statewide improvements to reduce the incidence of patient injuries.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

This rule iterates forward requirements of a repealed rule that is being renumbered. The UDOH determines enactment of this rule will not create any cost or savings impact to the state budget or UDOH's budget, since the renumbered rule will not increase workload and can be carried out with existing budget.

B) Local governments:

This filing does not create any direct cost or savings impact to local governments since they are not directly affected by this rule; nor are local governments indirectly impacted because this rule does not create a situation requiring services from local governments.

C) Small businesses ("small business" means a business employing 1-49 persons):

There will be no fiscal impact to small businesses because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

There will be no fiscal impact to non-small businesses because all requirements outlined in this rule still exist.

The requirements have been moved from a different title and rule.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

There will be no fiscal impact to persons other than small businesses, non-small businesses, state, or local government entities because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule.

F) Compliance costs for affected persons:

There will be no fiscal impact to affected persons because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table				
Fiscal Cost	FY2022	FY2023	FY2024	
State Government	\$0	\$0	\$0	
Local Governments	\$0	\$0	\$0	
Small Businesses	\$0	\$0	\$0	
Non-Small Businesses	\$0	\$0	\$0	
Other Persons	\$0	\$0	\$0	
Total Fiscal Cost	\$0	\$0	\$0	
Fiscal Benefits				
State Government	\$0	\$0	\$0	
Local Governments	\$0	\$0	\$0	
Small Businesses	\$0	\$0	\$0	
Non-Small Businesses	\$0	\$0	\$0	
Other Persons	\$0	\$0	\$0	
Total Fiscal Benefits	\$0	\$0	\$0	

Net Fiscal	\$0	\$0	\$0
Benefits			

H) Department head approval of regulatory impact analysis:

The Executive Director of the Department of Health, Rich Saunders, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

There is no fiscal impact on businesses because there are no additional requirements.

B) Name and title of department head commenting on the fiscal impacts:

Rich Saunders, Executive Director

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Subsection	Subsection	Subsection
26-1-30(3)	26-1-30(4)	26-1-30(6)
Subsection	Subsection	Subsection
26-1-30(7)	26-1-30(8)	26-1-30(9)
Section 26-3-7	Section 26-3-8	

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

	Rich Saunders, Executive Director	 04/23/2021
and title:		

R429. Health, Patient Safety Program.

R429-2. Health Care Facility Patient Safety Program. R429-2-1. Purpose and Authority.

(1) This rule establishes the requirement for designated facilities to have a patient safety program and effective internal patient safety processes for specified problems. The reporting under this rule will also help the Department and health care providers to understand patterns of system failures in the health care delivery system and, where appropriate, to recommend statewide improvements to reduce the incidence of patient injuries. It limits access to identifiable health information that facilities report to the Department under this rule.

(2) This rule is authorized by Section 26-3-8; Subsection 26-1-3(3); Subsection 26-1-30(4); Subsection 26-1-30(6) through Subsection 26-1-30(9).

R429-2-2. Definitions.

(1) "Adverse drug event" means any event involving a medication that causes or leads to patient harm while the medication is in the control of the facility. Such events may be related to professional practice, health care products, procedures, and systems, including: prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

(2) "Department" means the Utah Department of Health;

(3) "Facility" means a general acute hospital, critical access hospital, ambulatory surgical center, psychiatric hospital, orthopedic hospital, rehabilitation hospital, chemical dependency or substance abuse hospital or chronic disease hospital as those terms are defined inTitle 26, Chapter 25, Part 1, General Provisions.

(4) "Harm" means death or temporary or permanent impairment of body function or structure requiring intervention such as:

(a) a change in monitoring the patient's condition;

(b) a change in therapy; or

(c) active medical or surgical treatment.

R429-2-3. Patient Injury Identification.

(1) Each facility shall implement processes to effectively identify and report to the Department the incidence of each adverse drug event.

(2) Each facility shall report to the Department through established, statewide, electronic health care facility reporting systems managed by the Department.

(3) The report shall include codes applicable to the event from the current International Classification of Diseases Clinical Modification (ICD-CM) diagnosis coding, including codes for external cause of injury and codes for place of occurrence.

R429-2-4. Patient Injury Reduction.

(1) Each facility shall implement processes that are effective in reducing the incidence of adverse drug events.

R429-2-5. Confidentiality.

(1) Information received and stored by the Department under this rule may only be disclosed with Department approval under specific, enumerated conditions provided by Section 26-3-7. The Department is authorized to exercise its discretion to disclose information under the conditions of Section 26-3-8.

(2) The Department may not release information collected under this rule to any person pursuant to Subsection 26-3-7(1) or Subsection 26-3-7(8).

(3) Information provided by a facility to the Department under this rule is privileged, as provided by Title 26, Chapter 25, Confidential Information Release, and is not subject to discovery, use, or receipt in evidence in any legal proceeding of any kind or character.

R429-2-6. Penalties.

Any association, or corporation, or the officers of any of them, that violates any provision of this rule may be assessed a judicial civil or administrative money penalty not to exceed the sum of \$5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor as provided in Section 26-23-6.

KEY: hospital, sentinel event, quality improvement, patient safety

Date of Enactment or Last Substantive Amendment: 2021 Authorizing, and Implemented or Interpreted Law: 26-1-30(3); 26-1-30(4); 26-1-30(6); 26-1-30(7); 26-1-30(8); 26-1-30(9); 26-3-7; 26-3-8

NOTICE OF PROPOSED RULE			
TYPE OF RULE: New			
Utah Admin. Code Ref (R no.):	Utah Admin. Code R429-3 Filing No. Ref (R no.): 53441		

Agency Information

1. Department:	Health	Health		
Agency:	Patient Safety Program			
Room no.:	106	106		
Building:	Cannon			
Street address:	288 N 14	460 W		
City, state:	Salt Lak	e City, UT 84116		
Mailing address:	PO 1440	PO 144004		
City, state, zip:	Salt Lak	e City, UT 84114-4004		
Contact person(s	s):			
Name:	Phone:	Email:		
Carl Letamendi	801- 538- 7072	cletamendi@utah.gov		
Stephanie Saperstein	801- 538- 6430	stephaniesaperstein@utah.go v		

Mike Martin	801- 538- 9205	mikemartin@utah.gov
Please address on notice to the ager		regarding information on this

General Information

2. Rule or section catchline:

R429-3. Adverse Events from the Administration of Sedation or Anesthesia; Recording and Reporting

3. Purpose of the new rule or reason for the change:

This rule and its requirements existed under Rule R434-150 and is now being moved under the new Title R429. Rule R429-3 is a new rule that has been renumbered to align more appropriately with current, rule ownership within the Utah Department of Health (UDOH). Rule R429-3 has been updated to comply with rulewriting manual standards. Also, penalty language in Rule R429-3 has been updated for consistency with current statute. (EDITOR'S NOTE: The proposed repeal of Rule R434-150 is under Filing No. 53443 in this issue, June 15, 2021, of the Bulletin.)

4. Summary of the new rule or change:

This new, renumbered rule establishes requirements for reporting to UDOH Anesthesia Adverse Events Database including the report of reports and what constitutes a reportable adverse event.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

This rule iterates forward requirements of a repealed rule that is being renumbered. UDOH determines enactment of this rule will not create any cost or savings impact to the state budget or UDOH's budget, since the renumbered rule will not increase workload and can be carried out with existing budget.

B) Local governments:

This filing does not create any direct cost or savings impact to local governments since they are not directly affected by this rule; nor are local governments indirectly impacted because this rule does not create a situation requiring services from local governments.

C) Small businesses ("small business" means a business employing 1-49 persons):

There will be no fiscal impact to small businesses because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule. **D) Non-small businesses** ("non-small business" means a business employing 50 or more persons):

There will be no fiscal impact to non-small businesses because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

There will be no fiscal impact to persons other than small businesses, non-small businesses, state, or local government entities because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule.

F) Compliance costs for affected persons:

There will be no fiscal impact to affected persons because all requirements outlined in this rule still exist. The requirements have been moved from a different title and rule.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table			
Fiscal Cost	FY2022	FY2023	FY2024
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits			
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0

Other Persons	\$0	\$0	\$0	
Total Fiscal Benefits	\$0	\$0	\$0	
Net Fiscal Benefits	\$0	\$0	\$0	

H) Department head approval of regulatory impact analysis:

The Executive Director of the Department of Health, Rich Saunders, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

There is no fiscal impact on businesses because there are no additional requirements.

B) Name and title of department head commenting on the fiscal impacts:

Rich Saunders, Executive Director

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Section 26-1-40 Section 26-3-7

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

Agency head or designee, and title:	Rich Saunders, Executive Director	Date:	04/23/2021
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R429. Health, Patient Safety Program.

R429-3. Adverse Events from the Administration of Sedation or Anesthesia; Recording and Reporting.

R429-3-1. Purpose and Authority.

(1) The purpose of this rule is to establish reporting requirements to the Utah Department of Health Anesthesia Adverse Events Database that include the format of the reports and what constitutes a reportable adverse event.

(2) This rule is authorized by Title 26, Chapter 1, Part 40, Reports of anesthesia adverse events -- Whistle blower protections.

R429-3-2. Definitions.

(1) "Adverse event" means a reportable event that occurs:

(a) due to the administration of sedation or anesthesia;

(b) in an outpatient, non-emergency room setting;

(c) resulting in harm, escalation of care, or rescuing of the patient; and

(d) while under the direct care of the provider at the facility or within 24 hours of discharge.

(2) "Department" means the Utah Department of Health.

(3) "Escalation of care or rescue of a patient" means efforts made to rescue a patient from levels of sedation deeper than intended in order to prevent harm or death to a patient. This may include the use of:

(a) a rescue or reversal agent;

(b) aborting a procedure secondary to complications of sedation or anesthesia;

(c) unplanned assisted airway management;

(d) 911 call for Emergency Medical Services;

(e) transfer to a higher level of care; or

(f) any other intervention.

(4) "Harm scale" means a systematic method of designating a patient's level of harm that includes:

(a) unsafe conditions;

(b) near miss;

(c) no harm;

(d) additional monitoring or treatment to prevent harm;

(e) temporary harm requiring intervention;

(f) temporary harm requiring hospitalization;

(g) permanent patient harm;

(h) intervention to sustain life; or

(i) patient death.

(5) "Healthcare Provider" means any healthcare provider who uses sedation or anesthesia and is located in any outpatient location,including office settings, urgent care facilities, dental offices, and podiatry offices.

(6) "Levels of sedation" means physiologic states that are induced through the administration of medication by any route as established with standards associated with differing level of sedation set out in 42 CFR Subsection 482.51(b)(5). These interpretive guidelines are the expected standards of practice, unless otherwise specified by the individual practitioner's scope of practice as defined in Title 58, Chapter 67-502(5) Utah Medical Practice Act.

(7) "Near miss" means stopping or aborting a procedure for the safety of the patient.

(8) "Unprofessional Conduct" is defined in statute for each Utah Department of Professional licensure category in Sections 58-5a-502, 58-31b-502.5, 58-67-502.5, 58-68-502.5, and 58-69-502.5.

R429-3-3. Event Reporting.

(1) Once an adverse event has been determined by a licensed healthcare provider, and the provider or providers who administered the sedation or anesthesia involved in the event have been notified, the adverse event shall be reported to the Department within 72 hours.

(2) An individual reporting an event to the Anesthesia Adverse Event Database must register with the state.

(3) The reporting individual shall submit the following data and information at the time of the report:

(a) the person who reports the event;

(b) the healthcare provider and facility type that conducted the procedure;

(c) the healthcare provider and facility type that administered the anesthesia;

(d) a description of the event;

(e) a description of the sedation used;

(f) the level of harm experienced;

(g) the patient's demographics, including birthdate, gender, weight, race, and ethnicity if available:

(h) the surgical classification of the procedure, using American Society of Anesthesiologist physical status classification system;

(i) a description of rescue activities;

(j) a description of monitoring that took place:

(k) a description of escalation of care;

(1) a description of emergency equipment and supplies available at the time of the event; and

(m) any additional or concluding remarks.

R429-3-4. Confidentiality.

(1) Information received and stored by the Department under this rule may only be disclosed with Department approval under specific, enumerated conditions provided by Section 26-3-7. The Department is authorized to exercise its discretion to disclose information under the conditions of Section 26-3-8.

(2) The Department may not release information collected under this rule to any person pursuant to Subsections 26-3-7(1) and 26-3-7(8).

(3) Information provided by a facility to the Department under this rule is privileged, as provided by Title 26, Chapter 25, Confidential Information Release, and is not subject to discovery, use, or receipt in evidence in any legal proceeding of any kind or character.

R429-3-5. Extensions and Waivers.

(1) The Department may grant an extension of any reporting time requirement of this rule, if the facility demonstrates that:

(a) the delay is due to factors beyond its control;

(b) the delay will not adversely affect the purposes of this rule; or

(c) any other reason acceptable to the Department.

(2) A facility requesting a waiver shall submit its request to the Department representative prior to the deadline for the required action. (3) The Department may grant a waiver of any other provision of this rule if the facility demonstrates that the waiver will not adversely affect the Department's root cause analysis and the purposes of this rule.

R429-3-6. Annual Aggregate Reports.

(1) The Department's Anesthesia Adverse Event Database program manager shall report the following information to the legislature annually:

(a) a number of deaths and adverse events;

(b) a distribution of provider types involved in events by license category and specialty;

(c) the types of facility where events occurred;

(d) the number of non-provider reports;

(e) the procedures being performed when events occurred; and

(f) an analysis of the impact of these reporting requirements in reducing adverse events.

R429-3-7. Penalties.

Any association, or corporation, or the officers of any of them, that violates any provision of this rule may be assessed a judicial civil or administrative money penalty not to exceed the sum of \$5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor as provided in Section <u>26-23-6.</u>

KEY: anesthesia adverse events, patient safety, sedation related events

Date of Enactment or Last Substantive Amendment: 2021 Authorizing, and Implemented or Interpreted Law: 26-1-40; 26-3-7

NOTICE OF PROPOSED RULE		
TYPE OF RULE: Re	epeal	
Utah Admin. Code Ref (R no.):	R434-150	Filing No. 53443

Agency Information

1. Department:	Health		
Agency:	Family Health and Preparedness, Primary Care and Rural Health		
Room no.:	106		
Building:	Cannon		
Street address:	288 N 1	460 W	
City, state:	Salt Lake City, UT 84116		
Mailing address:	PO Box 144004		
City, state, zip:	Salt Lake City, UT 84114-4004		
Contact person(s	s):		
Name:	Phone:	Email:	
Carl Letamendi	801- 538- 7072	cletamendi@utah.gov	

Stephanie Saperstein	801- 538- 6430	stephaniesaperstein@utah.go v
Mike Martin	801- 538- 9205	mikemartin@utah.gov
Please address	s question	s regarding information on this

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

R434-150. Adverse Events from the Administration of Sedation or Anesthesia; Recording and Reporting

3. Purpose of the new rule or reason for the change:

This rule is being renumbered and also moved under a new title to better identify ownership of the Patient Safety Surveillance and Improvement program (PSSIP) within the Utah Department of Health (UDOH).

4. Summary of the new rule or change:

Rule R434-150 is being repealed and then recreated within the new Title R429 under a separate filing. Rule R434-150 can be repealed without any effect on work currently performed by the UDOH. Therefore, this rule is no longer needed and is repealed in its entirety. (EDITOR'S NOTE: The proposed new Rule R429-3 is under Filing No. 53441 in this issue, June 15, 2021, of the Bulletin.)

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

There will be no fiscal impact to state budget because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

B) Local governments:

There will be no fiscal impact to local governments because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

C) Small businesses ("small business" means a business employing 1-49 persons):

There will be no fiscal impact to small businesses because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule. **D) Non-small businesses** ("non-small business" means a business employing 50 or more persons):

There will be no fiscal impact to non-small businesses because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

There will be no fiscal impact to persons other than small businesses, non-small businesses, state, or local government entities because all requirements outlined in the rule will still exist, they are only being moved to a different title.

F) Compliance costs for affected persons:

There will be no fiscal impact to affected persons because all requirements outlined in this rule will still exist. The requirements are only being moved to a different title and rule.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table			
Fiscal Cost	FY2022	FY2023	FY2024
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits			
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0

Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head approval of regulatory impact analysis:

The Executive Director of the Department of Health, Rich Saunders, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

There is no fiscal impact on businesses because there are no additional requirements.

B) Name and title of department head commenting on the fiscal impacts:

Rich Saunders, Executive Director

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Section 26-1-40

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

Agency head	Rich Saunders,	Date:	04/23/2021
or designee,	Executive Director		
and title:			

R434. Health, Family Health and Preparedness, Primary Care and Rural Health.

[R434-150. Adverse Events from the Administration of Sedation or Anesthesia; Recording and Reporting.

R434-150-1. Purpose and Authority.

(1) To establish reporting requirements to the Utah
Department of Health Anesthesia Adverse Events Database that include:
 (a) the format of the reports; and

(b) what constitutes a reportable adverse event.

R434-150-2. Definitions.

(1) "Adverse event" means a reportable event that includes:

(a) the administration of sedation or anesthesia;
 (b) in an outpatient, non-emergency room setting;

(c) that results in escalation of care, harm to, or rescue of the patient; and

 (d) while under the direct care of the provider at the facility or within 24 hours of discharge.

(2) "Department" means the Utah Department of Health.

(3) "Escalation of care or rescue of a patient" means rescuing a patient from levels of sedation deeper than intended in order to prevent harm or death to a patient. This may include but is not limited to the use of:

(a) a rescue or reversal agent;

 (b) aborting a procedure secondary to complications of sedation or anaesthesia;

(c) unplanned assisted airway management;

 (d) 911 call for Emergency Medical Services;

 (e) transfer to a higher level of care; or

 (f) any other intervention.

 (d) "Harm scale" means a systematic method of designating

 a patient's level of harm that includes:

 (a) unsafe conditions;

(b) near miss;

(c) no harm;

(d) additional monitoring or treatment to prevent harm;

(e) temporary harm requiring intervention;

(f) temporary harm requiring hospitalization;

(g) permanent patient harm;

(h) intervention to sustain life; or

(i) patient death.

(5) "Healthcare Providers" means any healthcare provider who uses sedation or anaesthesia and is located in any outpatient location (e.g., office, urgent care, dentists, podiatrist, etc.) who is not currently required to report under Rule R380-200.

(6) "Levels of sedation" means physiologic states that are induced through the administration of medication by any route. Standards associated with differing levels of sedation are defined in the Centers for Medicare and Medicaid Conditions of Participation Interpretive Guidelines 482.51(b)(5) Interpretive Guidelines (https://www.ems.gov/Regulations-and-

Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf. These interpretive guidelines are the expected standards of practice, unless otherwise specified by the individual practitioner's scope of practice as defined in the Utah Licensure Practice Act and Title 58 of the Utah Code. (7) "Near miss" means stopping or aborting a procedure for the safety of the patient due to the administration of anaesthesia or sedation.

(8) "Unprofessional Conduct" is defined in statute for each Utah Department of Professional licensure category. See Utah Code Sections 58-5a-502, 58-31b-502.5, 58-67-502.5, 58-68-502.5, and 58-69-502.5.

R434-150-3. Anesthesia Adverse Event Database.

(1) The Anesthesia Adverse Event Database is managed through the Department's anesthesia reporting system.

(2) The Department shall establish the event report format.

R434-150-4. Event Reporting.

(1) Once an adverse event has been determined by a licensed healthcare provider, and the provider(s) who administered the sedation or anesthesia involved in the event have been notified, the adverse event shall be reported to the Department within 72 hours.

(2) To report an event:

(a) The individual reporting the event must:

(i) register with the State of Utah to get a state ID; and

(ii) notify the program manager that they have registered.

(b) The program manager shall:

(a) verify the reporting registrant's Utah state ID; and

(b) give the reporting registrant access to report their case to the Anesthesia Adverse Event Database.

(3) The reporting individual shall submit the following data and information at the time of the report:

(a) The person who reports the event;

(b) The healthcare provider(s) and facility type who conducted the procedure;

(c) The healthcare provider(s) and facility type who administered the anesthesia:

(d) Description of the event;

(e) Description of the sedation used:

(f) Level of harm experienced;

 (g) Patient demographics (birthdate, gender, and weight), to give context to the event;

 (h) Surgical classification of the procedure, using American Society of Anesthesiologist physical status classification system;

(i) Description of rescue activities;

(j) Description of monitoring that took place:

(k) Description of escalation of care;

 (l) Description of emergency equipment and supplies available at the time of the event; and

(m) Any additional or concluding remarks.

R434-150-5. Confidentiality.

 (1) Information received and stored by the Department under this Rule may only be disclosed with Department approval under specific, enumerated conditions provided by Utah Code Section 26-3-7.
 Because of the public interest in fostering health care systems improvements, the Department is authorized Utah Code Section 26-3-8 to exercise its discretion to disclose information under those conditions.
 (a) However, the Department shall not release information collected under this Rule to any person pursuant to the provisions of Subsections (1) or (8) of Section 26-3-7.

(2) Information provided by a facility to the Department under this Rule is privileged, as provided by Utah Code Title 26, Chapter 25, and is not subject to discovery, use, or receipt in evidence in any legal proceeding of any kind or character.

R434-150-6. Extensions and Waivers.

 (1) The Department may grant an extension of any reporting time requirement of this rule, if the facility demonstrates that:
 (a) the delay is due to factors beyond its control,

(b) the delay will not adversely affect the purposes of this rule; or

(c) any other reason acceptable to the Department.

(2) A facility requesting a waiver shall submit its request to the Department representative prior to the deadline for the required action.

(3) The Department may grant a waiver of any other provision of this Rule if the facility demonstrates that the waiver will not adversely affect the Department's root cause analysis and the purposes of this Rule.

R434-150-7. Annual Aggregate Reports.

(1) The Department's Anesthesia Adverse Event Database program manager shall report the following information to the legislature and public annually:

(a) Number of deaths and adverse events;

(b) Distribution of provider types involved in events by license category and specialty;

(c) Types of facility where events occurred;

(d) Number of non-provider reports;

(e) Procedures being performed when events occurred; and
 (f) An analysis of the impact of these reporting requirements
 in reducing adverse events.

R434-150-8. Penalties.

(1) As provided in Utah Code Section 26-23-6, an entity or person who violates any provision of this rule may be:

(a) assessed a civil penalty not to exceed \$10,000;

(b) subject to criminal prosecution for:

(i) a first violation as a class B misdemeanor;

(ii) each subsequent similar violation within two years of the first violation as class A misdemeanor: and

(c) reported to DOPL for investigation of unprofessional conduct.

KEY: anesthesia adverse events, patient safety, sedation related events

Date of Enactment or Last Substantive Amendment: April 14, 2018 Authorizing, and Implemented or Interpreted Law: 26-1-40]

NOTICE OF PROPO	SED RULE	
TYPE OF RULE: Ar	nendment	
Utah Admin. Code Ref (R no.):	R698-8	Filing No. 53556

Agency Information

1. Department:	Public Safety
Agency:	Administration
Building:	Calvin Rampton Complex
Street address:	4501 S 2700 W First Floor
City, state:	Salt Lake City, UT 84119-5994
Mailing address:	PO Box 141775
City, state, zip:	Salt Lake City, UT 84114-1775

Contact person(s):		
Name:	Phone:	Email:

Kim Gibb	801- 556- 8198	kgibb@utah.gov
D 1 1 1		

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

R698-8. Local Public Safety and Firefighter Surviving Spouse Trust Fund

3. Purpose of the new rule or reason for the change:

These changes are being made as a result of an internal review of this rule. It was determined that requiring an agency to identify the number of eligible employees on 03/31/2017 when they are making a current election to participate in the trust fund does not make sense. The "certificate of eligible employees" form should reflect the number of eligible employees at the time the agency elects to participate.

In addition, it has been problematic to provide notice of delinquency in premium payments to the individual who signed the cost sharing agreement in some cases where an individual has vacated their position. It was determined that the notice should be provided to the agency rather than to a specific individual in order to facilitate communication and ensure that agencies are able to make delinquent payments as quickly as possible so they may continue with participation in the trust fund.

4. Summary of the new rule or change:

In Section R698-8-4, the date of 03/31/2017 is being removed, and the language is being changed to clarify that if an employer elects to participate in the trust fund, the certificate of eligible employees form should reflect the number of eligible employees as of the date the employer elects to participate rather than as of 03/31/2017.

In Section R698-8-5, if a participating agency becomes delinquent in their premium payments, the language change reflects that notice will be provided to the "participating agency" rather than the individual who signed the agreement. There have been circumstances where the individual who signed the agreement has vacated their position, which has caused difficulty in getting the notice to the correct individual. The Department of Public Safety (DPS) anticipates that this will facilitate the communication reaching the appropriate individual so that the situation can be resolved in a timely manner and the agency will remain covered by the trust fund.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

DPS does not anticipate any costs or savings to the state budget as a result of this rule change. The changes only clarify the date that the certificate of eligible employees should reflect and that the participating agency, rather than a single individual, will be notified of a delinquency in premium payments.

B) Local governments:

DPS does not anticipate any costs or savings to local governments as a result of this rule change. The changes only clarify the date that the certificate of eligible employees should reflect and that the participating agency, rather than a single individual, will be notified of a delinquency in premium payments.

C) Small businesses ("small business" means a business employing 1-49 persons):

DPS does not anticipate any costs or savings to small businesses as a result of this rule change. The changes only clarify the date that the certificate of eligible employees should reflect and that the participating agency, rather than a single individual, will be notified of a delinquency in premium payments.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

DPS does not anticipate any costs or savings to non-small businesses as a result of this rule change. The changes only clarify the date that the certificate of eligible employees should reflect and that the participating agency, rather than a single individual, will be notified of a delinguency in premium payments.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

DPS does not anticipate any costs or savings to persons other than small businesses, non-small businesses, state, or local government entities as a result of this rule change. The changes only clarify the date that the certificate of eligible employees should reflect and that the participating agency, rather than a single individual, will be notified of a delinquency in premium payments.

F) Compliance costs for affected persons:

There are no compliance costs for affected persons. The changes only clarify the date that the certificate of eligible employees should reflect and that the participating agency, rather than a single individual, will be notified of a delinquency in premium payments.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

	, , , , , , , , ,		
Regulatory Ir	-		
Fiscal Cost	FY2021	FY2022	FY2023
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits			
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

 H) Department head approval of regulatory impact analysis:

The Commissioner of the Department of Public Safety, Jess L. Anderson, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

This rule change will not have a fiscal impact on businesses. This rule addresses participation in the line of duty death trust fund, which is only available to local law enforcement and fire entities and does not affect businesses. In addition, the changes are technical in nature and will not result in any fiscal impact to those affected by the rule. B) Name and title of department head commenting on the fiscal impacts:

Jess L. Anderson, Commissioner

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Section 53-17-301

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted 07/15/2021 until:

10. This rule change MAY 07/22/2021 become effective on:

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

Agency head	Jess L. Anderson,	Date:	05/27/2021
or designee,	Commissioner		
and title:			

R698. Public Safety, Administration.

R698-8. Local Public Safety and Firefighter Surviving Spouse Trust Fund.

R698-8-1. Purpose.

The purpose of this rule is to establish procedures for implementation of the Public Safety Officer and Firefighter Line-of-Duty Death Act.

R698-8-2. Authority.

This rule is authorized by Section 53-17-301.

R698-8-3. Definitions.

(2) In addition:

(1) The terms used in this rule are defined in Section 53-17-

102.

(a) "department" means the Utah Department of Public Safety; and

(b) "participating agency" means an employer defined in Section 53-17-102 that has elected to participate in the trust fund.

R698-8-4. Participation Process.

(1) An employer that elects or is required to participate in the trust fund pursuant to Section 53-17-301 shall submit:

(a) a cost sharing agreement form approved by the board;

(b) a certificate of eligible employees form approved by the board that identifies the number of eligible members [as of March 31, 2017] at the time the employer elects to participate in the trust fund; and

(c) the required annual premium payment as determined by the board.

(2) The information described in Subsection R698-8-4(1) shall be addressed to the Commissioner's office of the Department of Public Safety, Attn. Trust Fund.

(3) The cost sharing agreement form shall contain the following:

(a) the name, address and phone number of the employer; and

(c) the name, mailing address and signature of the agency administrator completing the cost sharing agreement form.

R698-8-5. Annual Payment of Premiums.

(1) A participating agency shall continue to submit annual premium payments to the department in order to continue to participate in the trust fund.

(2) Annual premium payments shall be submitted to the department no later than June 30 of each year and shall be accompanied by an updated certificate of eligible employees form that identifies the number of eligible members as of March 31.

(3) If a participating agency fails to submit a premium payment as required in this subsection, the department shall notify the <u>participating</u> agency [administrator who completed the cost sharing agreement.] of the delinquency in premium payments.

(4) If after receipt of a delinquency notice the participating agency fails to submit the annual premium payment within 30 days of the date of the notice, the department shall:

(a) notify the <u>participating</u> agency [administrator who completed the cost sharing agreement] that the employer is no longer considered to be a participant in the trust fund; and

(b) include in the notice the total amount of premiums paid by the employer into the trust fund.

R698-8-5. Reimbursement of Health Coverage Costs.

(1) In the event of a line-of-duty death of a member, a participating agency may receive reimbursement for payment of health coverage premiums and contributions made to a health savings account as described in Section 53-17-201.

(2) To receive reimbursement for payments described in Subsection (1), the participating agency shall submit to the department:

(a) a request for reimbursement on a form approved by the board upon initial request; and

(b) a copy of the statement provided by the group health plan that includes the participating agency's costs for coverage upon initial request and each month thereafter.

(3) The request for reimbursement form shall include:

(a) the name of the spouse for whom coverage is provided;

(b) the name and date or birth for each child under the age of 26 for whom coverage is provided.

and

(4) If the member did not have a living spouse at the time of death, the request for reimbursement form shall include the name and date of birth for each child under the age of 26 for whom coverage is provided.

(5) An employer is only eligible for reimbursement of health care coverage costs from the trust fund for a line of duty death that occurred between July 1, 2005 and July 1, 2018 if the employer participated in the trust fund in compliance with Section R698-8-4 prior to July 1, 2018 and is current with premium payments.

(6) An employer is not eligible for reimbursement of health care coverage costs from the trust fund for a line of duty death if at the time the line of duty death occurs, the employer is not a participating agency in compliance with this rule.

R698-8-6. Discontinuation of Reimbursement of Health Coverage Costs.

(1) In the event of the death of a spouse or child for whom coverage is provided under Section 53-17-201, the participating agency shall submit to the department:

(a) a form approved by the board that includes;

(i) the name of the spouse or child that is deceased;

(ii) the individual's date of birth; and

(iii) the date of the individual's death.

(2) Upon receipt of the form described in Subsection (1), the department shall discontinue reimbursement of health coverage costs from the trust fund for the deceased individual.

(3) If reimbursement is being paid from the trust fund for health coverage costs to an employer for a child under the age of 26, reimbursement will be automatically discontinued when the child reaches the age of 26.

KEY: line-of-duty death, cost sharing agreement, surviving spouse trust fund

Date of Enactment or Last Substantive Amendment: <u>2021[January</u> 9, 2020]

Notice of Continuation: January 15, 2021

Authorizing, and Implemented or Interpreted Law: 53-17-301

End of the Notices of Proposed Rules Section

FIVE-YEAR NOTICES OF REVIEW AND STATEMENTS OF CONTINUATION

Within five years of an administrative rule's original enactment or last five-year review, the agency is required to review the rule. This review is intended to help the agency determine, and to notify the public, that the administrative rule in force is still authorized by statute and necessary. Upon reviewing a rule, an agency may: repeal the rule by filing a **PROPOSED RULE**; continue the rule as it is by filing a **FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION (REVIEW)**; or amend the rule by filing a **PROPOSED RULE** and by filing a **REVIEW**. By filing a **REVIEW**, the agency indicates that the rule is still necessary.

A **Review** is not followed by the rule text. The rule text that is being continued may be found in the online edition of the *Utah Administrative Code* available at https://rules.utah.gov/. The rule text may also be inspected at the agency or the Office of Administrative Rules. **Reviews** are effective upon filing.

REVIEWS are governed by Section 63G-3-305.

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Utah Admin. Code R23-25 Filing No. 50037 Ref (R no.):

Agency Information

1. Department:	Administrative Services			
Agency:	Facilities		Construction	and
	Manage	ment		
Room no.:	Third Flo	or		
Building:	Taylorsv	ille Sta	ate Office Building	
Street address:	4315 S 2700 W			
City, state, zip:	Taylorsville, UT 84129-2128			
Mailing address:	PO Box 141160			
City, state, zip:	Salt Lake City, UT 84114-1160			
Contact person(s)):			
Name:	Phone:	Emai	1:	
Jim Russell	801-	jimru	ssell@utah.gov	
	957- 7191			
Please address ou	Please address questions regarding information on this			

Please address questions regarding information on this notice to the agency.

General Information

2. Rule catchline:

R23-25. Administrative Rules Adjudicative Proceedings

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

This rule is enacted under Subsection 36A-5b-305(2)(c). This Title 36A, Chapter 5b, allows the Division of Facilities Construction and Management (DFCM) or its director to make rules necessary to perform their duties.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

No written comments have been received for this rule during and since this rule's last five-year review.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

Rule R23-25 is necessary for DFCM to comply with the Utah Administrative Procedures Act, Section 63G-4-101 et seq. Therefore, this rule should be continued.

Agency Authorization Information

Agency head or designee, and title:	James R. Russell, DFCM Director	Date:	05/26/2021
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FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Utah Admin. Code	R23-31	Filing No. 50036
Ref (R no.):		_

Agency Information

1. Department:	Administrative Services		
Agency:	Facilities Construction and Management		
Room no.:	Third Floor		
Building:	Taylorsville State Office Building		
Street address:	4315 S 2700 W		
City, state, zip:	Taylorsville, UT 84129-2128		
Mailing address:	PO Box 141160		

ty, state, zip:	Salt Lake City, UT 84114-1160		
ontact person(s)	:		
ame:	Phone:	Email:	
n Russell	801- 957- 7191	jimrussell@utah.gov	
		regarding information	

Please address questions regarding information on this notice to the agency.

General Information

2. Rule catchline:

R23-31. Executive Residence Commission

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

This rule is enacted under Subsection 36A-5b-305(2)(c). This Title 36A, Chapter 5b, allows the Division of Facilities Construction and Management (DFCM) or its director to make rules necessary to perform their duties.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

No written comments have been received for this rule during and since this rule's last five-year review.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

Rule R23-31 is necessary for DFCM to fulfill its obligations with respect to the executive residence. Therefore, this rule should be continued.

Agency Authorization Information

Agency head	James R. Russell,	Date:	05/26/2021
or designee,	DFCM Director		
and title:			

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Utah Admin. Code	R156-15a	Filing No. 52708
Ref (R no.):		

Agency Information

1. Department:	Commerce		
Agency:	Occupational and Professional Licensing		
Building:	Heber M. Wells Building		
Street address:	160 E 300 S		
City, state, zip:	Salt Lake City, UT 84111-2316		

Mailing address:	PO Box	PO Box 146741		
City, state, zip:	Salt Lak	Salt Lake City, UT 84114-6741		
Contact person(s):			
Name:	Phone: Email:			
Steve Duncombe	801- sduncombe@utah.gov 530- 6235			
Please address q notice to the agen		regarding information on this		

General Information

2. Rule catchline:

R156-15a. State Construction Code Administration and Adoption of Approved State Construction Code Rule

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Title 15A, Chapter 1, provides a number of duties to be performed by the Division of Occupational and Professional Licensing (Division) in conjunction with the Uniform Building Code Commission, which includes establishing rules for the following: Subsection 15A-1-203(11)(a) establishing the Unified Code Council; Subsection 15A-1-204(6)(b) adopting approved codes; Section 15A-1-206 adopting a code amendment review process; Subsection 15A-1-209(3)(a) adopting a standardized building permit form; and Subsection 15A-1-306(1)(f) adopting continuing education requirements for manufactured housing installer contractors.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Since this rule was last reviewed in June 2016, several proposed rule filings have been filed by the Division. However, no written comments have been received by the Division with respect to this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule should be continued as it provides a mechanism for the Division and the Uniform Building Code Commission to perform duties assigned to them as provided in Title 15A. This rule should also be continued as it provides information to persons participating in the construction industry about approved codes, methods of presenting code amendments for consideration, information about the appeal process for challenges to code enforcement, and information about standardized building permit forms.

Agency Authorization Information

	Mark B. Steinagel, Director	Date:	02/02/2021
and title:			

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION			
Utah Admin. Code Ref (R no.):	R156-54	Filing No. 50281	

Agency Information

1. Department:	Commer	ce		
Agency:	Occupat Licensin		and	Professional
Building:	Heber M	. Wells	Building	
Street address:	160 E 30)0 S		
City, state, zip:	Salt Lake City, UT 84111-2316			
Mailing address:	PO Box 146741			
City, state, zip:	Salt Lake City, UT 84114-6741			
Contact person(s):				
Name:	Phone:	Email:		
Jana Johansen	801- 530- 6621	janajoh	ansen@)utah.gov
Please address questions regarding information on this				

Please address questions regarding information on this notice to the agency.

General Information

2. Rule catchline:

R156-54. Radiologic Technologist, Radiologist Assistant, and Radiology Practical Technician Licensing Act Rule

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Title 58, Chapter 54, provides for the licensure and regulation of radiologic technologists, radiologist assistants, and radiology practical technicians. Subsection 58-1-106(1)(a) provides that the Division of Occupational and Professional Licensing (Division) may adopt and enforce rules to administer Title 58. Subsection 58-1-202(1)(a) provides that the Radiologic Technologist Licensing Board's duties, functions, and responsibilities includes recommending to the director appropriate rules. This rule was enacted to clarify the provisions of Title 58, Chapter 54, with respect to radiologic technologists, radiologist assistants, and radiology practical technicians.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule: Since this rule was last reviewed in June 2016, this rule has now been amended. Thus, the Division has received no written comments with respect to this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule should be continued as it provides a mechanism to inform potential licensees of the requirements for licensure as allowed under statutory authority provided in Title 58, Chapter 54. This rule should also be continued as it provides information to ensure applicants for licensure are adequately trained and meet minimum licensure requirements, and provides licensees with information concerning unprofessional conduct, definitions, and ethical standards relating to the profession.

Agency Authorization Information

Agency head	Mark B. Steinagel,	Date:	01/28/2021
or designee,	Director		
and title:			

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Utah Admin.	Code	R495-876	Filing No. 51169	
Ref (R no.):			_	

Agency Information

1. Department:	Human	Services		
Agency:	Adminis	tration		
Building:	MASOB			
Street address:	195 N 19	195 N 1950 W		
City, state, zip:	Salt Lak	Salt Lake City, UT 84116		
Contact person(s):				
Name:	Phone:	Email:		
Jonah Shaw	385- 310- 2389	jshaw@utah.gov		
Please address questions regarding information on this notice to the agency.				

General Information

2. Rule catchline:

R495-876. Provider Code of Conduct

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Section 62A-1-111 authorizes the Department to "adopt rules, not inconsistent with law, as the department may consider necessary or desirable for providing social services to the people of this state." This rule establishes a provider code of conduct to "protect its clients from abuse, neglect, maltreatment and exploitation, and clarify the expectation of conduct for Department of Human Services (DHS) Providers and their employees and volunteers who interact in any way with DHS clients, DHS staff, and the public."

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

No written comments were received.

A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

The continuation of this rule is essential to meet the requirements of Section 62A-1-111 and to establish the provider code of conduct to "protect its clients from abuse, neglect, maltreatment and exploitation, and clarify the expectation of conduct for DHS Providers and their employees and volunteers who interact in any way with DHS clients, DHS staff, and the public."

Agency Authorization Information

0 3	Nate Checketts, Deputy Director	Date:	05/28/2021
and title:			

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION Utah Admin. Code R495-880 Filing No. 51176 Ref (R no.):

Agency Information

0 ,				
1. Department:	Human	Human Services		
Agency:	Adminis	tration		
Building:	MASOB			
Street address:	195 N 1	950 W		
City, state, zip:	Salt Lak	Salt Lake City, UT 84116		
Contact person(s):				
Name:	Phone:	Phone: Email:		
Jonah Shaw	385- 310- 2389	jshaw@utah.gov		
Please address questions regarding information on this notice to the agency.				

General Information

2. Rule catchline:

R495-880. Adoption Assistance

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Section 62A-4a-905 requires the Department shall "by rule, establish in each region at least one advisory committee to review and make recommendations to the division on individual requests for supplemental adoption assistance."

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

No written comments were received.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

The continuation of this rule is essential to meet the requirements of Section 62A-4a-905 as this establishes the advisory committee in rule and references this rule that establishes a threshold amount for requests for supplemental adoption assistance that require review from the committee.

Agency Authorization Information

or designee,	Nate Checketts, Deputy Director	Date:	05/28/2021
and title:			

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Utah Admin. Code	R661-9	Filing No. 52701
Ref (R no.):		-

Agency Information

1. Department:	Navajo Trust Fund			
Agency:	Trustees			
Street address:	151 E 500 N			
City, state, zip:	Blanding, UT 84511			
Contact person(s):				
Name:	Phone: Email:			
Maury Bergman	435- 678- 1461	mbergman@utah.gov		
Tony Dayish	435- tdayish@utah.gov 678- 1468			
Please address questions regarding information on this notice to the agency.				

FIVE-YEAR NOTICES OF REVIEW AND STATEMENTS OF CONTINUATION

General Information

2. Rule catchline:

R661-9. Utah Navajo Trust Fund Public Facility Projects

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Statutory provisions are under Subsection 51-10-205(4): The Trust Administrator shall make rules in accordance with Subsection (6) that establish policies and criteria for expenditure of fund money.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

No comments have been received since the last five-year review of this rule from interested persons.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule should be continued because it enables the Utah Navajo Trust Fund to fund in part or in its entirety public facilities such as chapter houses, warehouses, multipurpose buildings, senior centers, wellness or recreational facilities, day care centers, etc. No negative comments have been received from the public regarding the funding of public facilities.

Agency Authorization Information

Agency head	Tony Dayish,	Date:	05/20/2021
or designee,	Administrator		
and title:			

 	 	 E OF REVIEW AN	D	
 	-			

Utah Admin. Code	R661-10	Filing No. 52702
Ref (R no.):		_

Agency Information

1. Department:	Navajo Trust Fund		
Agency:	Trustees		
Street address:	151 E 500 N		
City, state, zip:	Blanding, UT 84511		
Contact person(s):			
Name:	Phone:	Email:	
Maury Bergman	435- 678- 1461	mbergman@utah.gov	

Tony Dayish	435- 678- 1468	tdayish@utah.gov		
Please address questions regarding information on this notice to the agency.				

General Information

2. Rule catchline:

R661-10. Utah Navajo Trust Fund Short-Term Training Program

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Statutory provisions are under Subsection 51-10-205(4): The Trust Administrator shall make rules in accordance with Subsection (6) that establish policies and criteria for expenditure of fund money.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

No comments have been received since the last five-year review of this rule from interested persons.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule should be continued because it enables the Utah Navajo Trust Fund to fund short term training programs for Utah Navajos such as Commercial Driver's Licenses, Heavy Equipment Operator's License and Welders Certificates etc. No negative comments have been received from the public regarding the funding of public facilities.

Agency Authorization Information

or designee, Administrator and title:
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FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Utah Admin. Code	R661-11	Filing No. 51793
Ref (R no.):		_

Agency Information

1. Department:	Navajo Trust Fund	
Agency:	Trustees	
Street address:	151 E 500 N	
City, state, zip:	Blanding, UT 84511	

Contact person(s):			
Phone:	Email:		
435- 678- 1461	mbergman@utah.gov		
435- 678- 1468	tdayish@utah.gov		
	Phone: 435- 678- 1461 435- 678-		

notice to the agency.

General Information

2. Rule catchline:

R661-11. Utah Navajo Trust Fund Water Development Projects Culinary and Septic Systems

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Statutory provisions are under Subsection 51-10-205(4): The Trust Administrator shall make rules in accordance with Subsection (6) that establish policies and criteria for expenditure of fund money.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

No comments have been received since the last five-year review of this rule from interested persons.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule should be continued because it enables the Utah Navajo Trust Fund to fund individuals and entities for Water Development Projects, culinary and septic leach field development, and development of wells for culinary, agricultural, or livestock water systems. No comments in opposition have been received.

Agency Authorization Information

Agency head	Tony Dayish,	Date:	05/20/2021
or designee,	Administrator		
and title:			

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Utah Admin. Code	R661-12	Filing No. 51802
Ref (R no.):		-

Agency Information

1. Department:	Navajo Trust Fund	
Agency:	Trustees	

Street address:	151 E 50	151 E 500 N		
City, state, zip:	Blanding	Blanding, UT 84511		
Contact person(s):				
Name:	Phone:	Phone: Email:		
Maury Bergman	435- 678- 1461	mbergman@utah.gov		
Tony Dayish	435- 678- 1468	tdayish@utah.gov		

Please address questions regarding information on this notice to the agency.

General Information

2. Rule catchline:

R661-12. Utah Navajo Trust Fund Homesite Lease Assistance Program

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Statutory provisions are under Subsection 51-10-205(4): The Trust Administrator shall make rules in accordance with Subsection (6) that establish policies and criteria for expenditure of fund money.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

No comments have been received since the last five-year review of this rule from interested persons.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule should be continued because it enables the Utah Navajo Trust Fund to fund the costs associated with obtaining a Homesite Lease for eligible families for the purpose of building a house. No comments in opposition to this rule have been received.

Agency Authorization Information

Agency head or designee,	Tony Dayish, Administrator	Date:	05/20/2021
and title:			

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION Utah Admin, Code R710-11 Filing No. 51910

	1 ming 110. 01010
Ref (R no.):	

Agency Information

1. Department:	Public Safety			
Agency:	Fire Mar	Fire Marshal		
Street address:	410 W 9	800 S, Suite 372		
City, state, zip:	Sandy, l	JT 84070		
Contact person(s):				
Name:	Phone: Email:			
Kim Gibb	801- 556- 8198	kgibb@utah.gov		
Coy Porter	801- 256- 2383	coyporter@utah.gov		
Ted Black	801- 256- 2380	tblack@utah.gov		

Please address questions regarding information on this notice to the agency.

General Information

2. Rule catchline:

R710-11. Fire Alarm System Inspecting and Testing

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

This rule is authorized by Section 53-7-204. The Utah Fire Prevention Board is created within the Division of the Fire Marshal under Section 53-7-203. The board is required under Subsection 53-7-204(1)(b) to make rules to establish standards for the prevention of fire and for the protection of life and property against fire.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

There have been no written comments received during and since the last five-year review of this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

Fire alarm systems and the maintenance and inspection of fire alarm systems are integral to ensuring life safety. This rule outlines the requirements to obtain a certificate of registration for the purposes of inspecting and testing fire alarm systems, standards, and procedural requirements for the purposes of servicing fire alarm systems, and adjudicative proceedings. Therefore, this rule should be continued.

Agency Authorization Information

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION			
Utah Admin. Code	Utah Admin. Code R940-1 Filing No. 52251		
Ref (R no.):	Ref (R no.):		

Agency Information

.gonoy mornation				
1. Department:	Transportaion Commission			
Agency:	Administration			
Room no.:	First Flo	or Administration Suite		
Building:	Calvin R	ampton		
Street address:	4501 S 2	2700 W		
City, state, zip:	Salt Lak	e City, UT 84129		
Mailing address:	PO Box	148455		
City, state, zip:	Salt Lak	e City, UT 84114-8455		
Contact person(s):				
Name:	Phone: Email:			
Linda Hull	801- 965- 4253	Ihull@utah.gov		
James Palmer	es Palmer 801- jimpalmer@agutah.gov 965- 4197			
Lori Edwards	801- loriedwards@agutah.gov 965- 4048			
Becky Lewis	801- blewis@utah.gov 965- 4026			
Please address questions regarding information on this				

Please address questions regarding information on this notice to the agency.

General Information

2. Rule catchline:

R940-1. Establishment of Toll Rates

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Subsection 72-6-118(6)(a)(i) requires the Transportation Commission (Commission) make rules that set the amount of any toll imposed or collected on a tollway on a state highway. This rule satisfies that mandate. 4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

The Department of Transportation has received no written comments during and since the last five-year review of this rule from interested persons supporting or opposing this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

Subsection 72-6-118(6)(a)(i) is still in effect so the Commission must maintain this rule. Therefore, this rule should be continued.

Agency Authorization Information

Agency head	Carlos M.	Date:	05/28/2021
or designee,	Braceras, PE,		
and title:	Executive		
	Director		

End of the Five-Year Notices of Review and Statements of Continuation Section

NOTICES OF FIVE-YEAR EXPIRATIONS

Rulewriting agencies are required by law to review each of their administrative rules within five years of the date of the rule's original enactment or the date of last review (Section 63G-3-305). The Office of Administrative Rules (Office) is required to notify agencies of rules due for review at least 180 days prior to the anniversary date. If the agency finds that it will not meet the deadline for review of the rule (the five-year anniversary date), it may file a **NOTICE OF FIVE-YEAR EXTENSION (EXTENSION)** with the Office. However, if the agency fails to file either the **FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION** or the **EXTENSION** by the date provide by the Office, the rule expires.

Upon expiration of the rule, the Office files a **NOTICE OF FIVE-YEAR EXPIRATION** (**EXPIRATION**) to document the action. The Office is required to remove the rule from the *Utah Administrative Code*. The agency may no longer enforce the rule and it must follow regular rulemaking procedures to replace the rule if it is still needed.

The Office has filed **EXPIRATIONS** for each of the rules listed below which were not reviewed in accordance with Section 63G-3-305. These rules have expired and have been removed from the *Utah Administrative Code*.

The expiration of administrative rules for failure to comply with the five-year review requirement is governed by Subsection 63G-3-305(8).

NOTICE OF EXPIRED RULE		
Utah Admin. Code Ref (R no.):	R450-3	Filing No. 51123

Agency	Information

1. Department:	Heritage and Arts			
Agency:	Adminis	Administration		
Street address:	300 S Rio Grande St			
City, state, zip:	Salt Lake City, UT 84101			
Contact person(s):				
Name:	Phone: Email:			
Nancy Lancaster	801- 957- 7102	rulesonline@utah.gov		

2. Title of rule (catchline):	
R450-3. Arts a Program Rules	nd Culture Business Alliance General
3. Effective Date:	05/27/2021
4. Summary:	
filed for this rule b	iew and notice of continuation was not y the deadline. This rule has expired and om the Administrative Code.

End of the Notices of Notices of Five Year Expirations Section

NOTICES OF RULE EFFECTIVE DATES

State law provides for agencies to make their administrative rules effective and enforceable after publication in the *Utah State Bulletin*. In the case of **PROPOSED RULES** or **CHANGES IN PROPOSED RULES** with a designated comment period, the law permits an agency to make a rule effective no fewer than seven calendar days after the close of the public comment period, nor more than 120 days after the publication date. In the case of **CHANGES IN PROPOSED RULES** with no designated comment period, the law permits an agency to make a rule effective on any date including or after the thirtieth day after the rule's publication date, but not more than 120 days after the publication date. If an agency fails to file a **NOTICE OF EFFECTIVE DATE** within 120 days from the publication of a **PROPOSED RULE** or a related **CHANGE IN PROPOSED RULE** the rule lapses.

Agencies have notified the Office of Administrative Rules that the rules listed below have been made effective.

NOTICES OF EFFECTIVE DATE are governed by Subsection 63G-3-301(12), Section 63G-3-303, and Sections R15-4-5a and R15-4-5b.

Agriculture and Food Animal Industry No. 53311 (Amendment) R58-21: Trichomoniasis Published: 02/15/2021 Effective: 06/04/2021

No. 53311 (Change in Proposed Rule) R58-21: Trichomoniasis Published: 04/15/2021 Effective: 06/04/2021

Plant Industry No. 53372 (Amendment) R68-27: Cannabis Cultivation Published: 04/01/2021 Effective: 05/15/2021

Regulatory Services No. 53379 (New Rule) R70-590: Utah Domesticated Game Slaughter and Processing Published: 04/15/2021 Effective: 06/04/2021

Commerce Administration No. 53373 (Amendment) R151-2: Government Records Access and Management Act Rule Published: 04/15/2021 Effective: 05/24/2021

Real Estate No. 53376 (Amendment) R162-2f: Real Estate Licensing and Practices Rules Published: 05/01/2021 Effective: 06/08/2021 Education Administration No. 53366 (Amendment) R277-214: Utah Professional Practices Advisory Commission Criminal Background Review Published: 04/01/2021 Effective: 05/24/2021

No. 53368 (Repeal) R277-504: Early Childhood, Elementary, Secondary, Special Education (K-12), and Preschool Special Education (Birth-Age 5) Licensure Published: 04/01/2021 Effective: 05/24/2021

No. 53369 (Repeal) R277-509: Licensure of Student Teachers and Interns Published: 04/01/2021 Effective: 05/24/2021

No. 53370 (Repeal) R277-511: Academic Pathway to Teaching (APT) Level 1 License Published: 04/01/2021 Effective: 05/24/2021

No. 53371 (Amendment) R277-617: Smart School Technology Program Published: 04/01/2021 Effective: 05/24/2021

Environmental Quality Administration No. 53378 (New Rule) R305-11: Clean Air Support Restricted Account Grant Program New Rule Published: 04/15/2021 Effective: 06/01/2021

NOTICES OF RULE EFFECTIVE DATES

Governor Economic Development No. 53418 (Amendment) R357-25: Rural Coworking and Innovation Center Grant Program Published: 05/01/2021 Effective: 06/08/2021

Health Administration No. 53290 (New Rule) R380-412: Compassionate Use Board Published: 02/15/2021 Effective: 06/03/2021

Disease Control and Prevention, Health Promotion No. 53257 (Amendment) R384-415: Electronic Cigarette Substance Standards Published: 01/15/2021 Effective: 06/01/2021

Disease Control and Prevention, Health Promotion No. 53257 (Change in Proposed Rule) R384-415: Electronic Cigarette Substance Standards Published: 03/15/2021 Effective: 06/01/2021

Health Care Financing, Coverage and Reimbursement Policy No. 53359 (Amendment) R414-60: Limitations Published: 04/01/2021 Effective: 05/12/2021

No. 53360 (Amendment) R414-510: Intermediate Care Facility for Persons with Intellectual Disabilities Transition Program and Education Published: 04/01/2021 Effective: 05/12/2021

Center for Health Data, Vital Records and Statistics No. 53374 (Repeal and Reenact) R436-2: Infants of Unknown Parentage; Foundling Registration Published: 04/15/2021 Effective: 05/26/2021

Human Services Recovery Services No. 53388 (Amendment) R527-250: Emancipation Published: 04/15/2021 Effective: 05/24/2021

Insurance Administration No. 53271 (Amendment) R590-102: Insurance Department Fee Payment Rule Published: 01/15/2021 Effective: 05/24/2021 No. 53271 (Change in Proposed Rule) R590-102: Insurance Department Fee Payment Rule Published: 04/15/2021 Effective: 05/24/2021

Title and Escrow Commission No. 53375 (Amendment) R592-6: Unfair Inducements and Marketing Practices in Obtaining Title Insurance Business Published: 04/15/2021 Effective: 05/24/2021

<u>Natural Resources</u> Oil, Gas and Mining; Oil and Gas No. 53303 (Amendment) R649-1: Oil and Gas Definitions Published: 02/15/2021 Effective: 05/27/2021

No. 53303 (Change in Proposed Rule) R649-1: Oil and Gas Definitions Published: 04/15/2021 Effective: 05/27/2021

No. 53306 (Amendment) R649-10: Administrative Procedures Published: 02/15/2021 Effective: 05/27/2021

No. 53306 (Change in Proposed Rule) R649-10: Administrative Procedures Published: 04/15/2021 Effective: 05/27/2021

No. 53305 (New Rule) R649-11: Administrative Penalties Published: 02/15/2021 Effective: 05/27/2021

No. 53305 (Change in Proposed Rule) R649-11: Administrative Penalties Published: 04/15/2021 Effective: 05/27/2021

Public Safety Driver License No. 53384 (Repeal) R708-18: Regulatory and Administrative Fees Published: 04/15/2021 Effective: 05/25/2021

School and Institutional Trust Lands Administration No. 53407 (Repeal and Reenact) R850-80: Sale of Trust Lands Published: 05/01/2021 Effective: 06/08/2021

End of the Notices of Rule Effective Dates Section